

4 IN RE: NATIONAL)
4 PRESCRIPTION) MDL No. 2804
4 OPIATE LITIGATION)
5 _____) Case No.
5) 1:17-MD-2804
6)
6 THIS DOCUMENT RELATES) Hon. Dan A.
7 TO ALL CASES) Polster

FRIDAY, NOVEMBER 16, 2018

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

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1	Mallinckrodt Rausch 5	Mallinckrodt Controlled Substance Suspicious Order Monitoring Program, Introductory Training for Field Sales, June 5, 2008	126	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
2				VIDEOPHAGER: We're now on the record. My name is James Arndt. I'm a videographer for Golkow Litigation Services.
3				Today's date is November 16, 2018, and the time is 9 a.m.
4	Mallinckrodt Rausch 6	DEA Compliance Procedure, Draft 3, published 6/2/08, MNK-T1_0000419993 - MNK-T1_0000419997	151	This video deposition is being held in St. Louis, Missouri, in the matter of the National Prescription Opiate Litigation for the United States District Court, Northern District of Ohio, Eastern Division.
5	Mallinckrodt Rausch 7	Suspicious Order Monitoring Program, Dosage Products Shipment from Hobart, Activities 08/2008 through 08/2010, MNK-T1_0000477900 - MNK-T1_0000477912	196	The deponent is Jim Rausch.
6	Mallinckrodt Rausch 8	Peculiar Order Process, MNK-T1_0000264431 - MNK-T1_0000264432	231	Will counsel please identify themselves for the record?
7	Mallinckrodt Rausch 9	November 2, 2010 Memorandum from Howard Davis to Karen Harper, MNK-T1_0000269399 - MNK-T1_0000269400	236	MR. KAWAMOTO: Dean Kawamoto, Gary Gotto and Erika Keech from Keller Rohrback on behalf of the MDL plaintiffs.
8	Mallinckrodt Rausch 10	Standard Operating Procedure, Due diligence procedures and monitoring of controlled substances sales, MNK-T1_0000269401 - MNK-T1_0000269406	244	MR. TSAI: Good morning. Rocky Tsai, Ropes & Gray, representing the witness and Mallinckrodt.
9	Mallinckrodt Rausch 11	E-mail(s), MNK-T1_0000307119	275	MR. DAVISON: William Davison, Ropes & Gray, representing the witness and Mallinckrodt.
10	Mallinckrodt Rausch 12	E-mail(s), MNK-T1_0000266788	279	
11	Mallinckrodt Rausch 13	E-mail(s), MNK-T1_0000266994 - MNK-T1_0000266997	282	
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1	Mallinckrodt Rausch 14	E-mail(s), MNK-T1_0000266735 - MNK-T1_0000266736	286	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
2	Mallinckrodt Rausch 15	E-mail(s), MNK-T1_0000266730	291	MR. TILLY: Jason Tilly, Mallinckrodt Pharmaceuticals.
3	Mallinckrodt Rausch 16	E-mail(s), MNK-T1_0000298447	293	MS. CONWAY: Sarah Conway on behalf of Walmart.
4	Mallinckrodt Rausch 17	E-mail(s), MNK-T1_0000387257 - MNK-T1_0000387258 (Exhibits attached to the deposition.)	298	MS. HERZFELD: Tricia Herzfeld on behalf of plaintiffs for the Tennessee state litigation.
5				VIDEOPHAGER: The court reporter is Carrie Campbell, and she will now swear in the witness.
6				MR. YINGLING: Yeah, this is Patrick Yingling for AmerisourceBergen.
7				MR. PERSKIE: Jacob Perskie from Fox Rothschild for Validus Pharmaceuticals in the Arkansas matter.
8				MS. YOCUM: Michelle Yocum from on behalf of McKesson.
9				MS. McNAMARA: Colleen McNamara on behalf of Cardinal Health.
10				MR. RICARD: Paul Ricard on behalf of Prescription Supply, Inc.
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<p>1 JAMES RAUSCH, 2 of lawful age, having been first duly sworn 3 to tell the truth, the whole truth and 4 nothing but the truth, deposes and says on 5 behalf of the Plaintiffs, as follows: 6</p> <p>7 DIRECT EXAMINATION 8 QUESTIONS BY MR. KAWAMOTO: 9 Q. Good morning, Mr. Rausch. 10 A. Good morning. 11 Q. Thank you for being here today. 12 So my name is Dean, and my 13 colleagues are Gary and Erika. 14 I'm going to plan to take a 15 break probably around every hour, but if you 16 need one earlier, just please let me know. 17 A. Okay. 18 Q. Could you please state your 19 name and business address? 20 A. James Rausch, and I'm currently 21 retired. 22 Q. And you understand that you're 23 under oath, right, sir? 24 A. Yes. 25 Q. And are you taking any</p>	<p>1 Your attorney may object for 2 the record. Unless he instructs you not to 3 answer, though, you are to answer the 4 question. 5 A. Okay. 6 Q. Have you ever testified at 7 trial? 8 A. One -- once. 9 Q. And can you describe the -- 10 well, what was the nature of that trial? 11 A. Someone stole firearms from my 12 house -- or my apartment at the time. I went 13 to testify on identifying the firearm. 14 Q. And who are the other people 15 seated next to you today? 16 A. These are the lawyers 17 representing Mallinckrodt. 18 Q. And are they also your 19 attorneys? 20 A. They represent me. 21 Q. Okay. And are you paying them 22 to be here today? 23 A. No. 24 Q. Okay. Do you know who is 25 paying them?</p>
<p>1 medications, or is there any other reason 2 that would interfere with your ability to 3 answer my questions fully and truthfully? 4 A. I'm taking medications, but it 5 wouldn't interfere with being able to answer 6 the questions. 7 Q. Thank you. 8 And if I ask a question you 9 don't understand, please let me know and I 10 will try to rephrase it. 11 A. Okay. 12 Q. Have you ever testified in a 13 deposition? 14 A. No. 15 Q. Okay. So some basic ground 16 rules, just primarily for the benefit of the 17 court reporter, but it's very important that 18 when I ask you a question, that you answer 19 verbally as opposed to nodding or shaking 20 your head. 21 A. Okay. 22 Q. And it's also very important 23 that we not speak over each other. So I'll 24 ask my question, and then I'll let you 25 answer.</p>	<p>1 A. Mallinckrodt. 2 Q. So, sir, I want to ask you a 3 few questions about your deposition 4 preparation. 5 Did you review any documents in 6 preparation for this deposition? 7 A. That's attorney-client 8 privilege. 9 Q. My understanding, and Rocky can 10 object if he feels he needs to, but I'm not 11 asking you to identify for me the documents 12 that you reviewed. I just want to know if 13 you reviewed any documents. 14 MR. TSAI: You can answer that 15 question. 16 THE WITNESS: Yes. 17 QUESTIONS BY MR. KAWAMOTO: 18 Q. Okay. And did you review any 19 deposition transcripts or other trial 20 testimony? 21 A. No. 22 Q. And did you review any expert 23 reports? 24 A. Excerpt reports? 25 Q. Expert reports.</p>

	Page 14	Page 16
1	A. No.	ask you to identify those -- I will
2	Q. My apologies.	ask you to identify those documents.
3	Do you recall reviewing any	Rocky?
4	court documents?	MR. TSAI: I object on
5	A. No.	attorney-client privilege and work
6	Q. And what about any electronic	product grounds, and I instruct the
7	records, for example, any databases?	witness not to answer to the extent
8	A. No.	the question is asking him to identify
9	Q. Now, have you looked at your	documents that were selected and
10	own personal paper or electronic files to	compiled by counsel and discussed with
11	prepare for this deposition?	counsel.
12	A. No, I've been retired for	QUESTIONS BY MR. KAWAMOTO:
13	almost six years.	Q. Okay. So I'm going to try to
14	Q. Now, I take it you spoke with	modify that question, and your attorney may
15	your attorneys prior to this deposition; is	also have the same objection.
16	that fair?	But can you generally describe
17	A. Yes.	for me the categories of documents that you
18	Q. And do you recall whether it	looked at to refresh your recollection?
19	was in person or by phone or both?	A. I believe that's
20	A. In person.	attorney-client privilege.
21	Q. And on how many occasions did	E-mails, I guess, would be the
22	you speak with them?	answer to that.
23	A. Three times.	Q. And other than your attorneys,
24	Q. And do you recall roughly how	did you speak to anyone else to prepare for
25	many hours on each occasion it was?	your deposition?
	Page 15	Page 17
1	A. Four or five hours, roughly.	A. No, sir.
2	Q. And this is four or five hours	Q. Okay. Now, sir, are you being
3	each time?	reimbursed by anyone for your expenses in
4	A. Yes.	connection with this deposition?
5	Q. Okay. And at these meetings,	A. No, sir.
6	who was present?	Q. And so Mallinckrodt is not
7	A. Rocky and Bill.	compensating you for your time in connection
8	Q. And so no one else was present	with this deposition?
9	other than --	A. No, sir.
10	A. No.	Q. Can you brief -- strike that.
11	Q. -- Rocky and Bill?	Can you briefly describe your
12	Now, you indicated that you	education background after high school?
13	reviewed documents.	A. I went to college for three
14	Did any of those documents	years in pursuit of a major in psychology,
15	refresh your recollection regarding the	and -- I was hired -- this was in '76, I was
16	issues at this deposition?	hired as -- at Mallinckrodt as a summer
17	A. Yes. Considering that I've	replacement for people going on vacation, and
18	been retired for six years, so I had not seen	I ended up staying on full time, so I never
19	any of these documents for quite a long time.	did finish school.
20	MR. KAWAMOTO: Okay. And I	Q. And roughly when you did you
21	take it, Mr. Tsai, if I ask him to	start working at Mallinckrodt?
22	identify those documents, you'll	A. 1976.
23	object on privilege?	Q. And you say you retired six
24	MR. TSAI: Yes.	years ago. So forgive my math, but that
25	MR. KAWAMOTO: Okay. So I will	would be 2012?

<p style="text-align: right;">Page 18</p> <p>1 A. 2013. January. 2 Q. Okay. And so between 1976 and 3 2013, you were employed by Mallinckrodt? 4 A. That's correct. 5 Q. And so you've never worked for 6 anyone else other than Mallinckrodt? 7 A. Correct. 8 Q. Have you completed any 9 nondegree programs of study? 10 And if you don't understand 11 what that means, I'm happy to clarify. 12 A. Would you clarify that? 13 Q. Have you taken any other 14 courses or any training outside of 15 Mallinckrodt, for example, any -- do you have 16 any regulatory certifications or professional 17 licenses? 18 A. No. 19 Q. So I would like to ask you 20 about your employment at Mallinckrodt, and 21 recognizing that it covers 1976 to 2013, it's 22 a broad time period, so I'll understand if 23 you don't remember the details, particularly 24 from the earlier time. 25 But can you generally walk me</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. And then when did you go to 2 production and inventory, roughly what year? 3 A. I would say '77. 4 Q. Okay. And I'm sorry, go ahead. 5 You were saying something about, I think it 6 was a bulk business? 7 A. Yes, the bulk business that 8 Mallinckrodt had there. I was a production 9 and inventory control planner. 10 Q. And what did that entail? I'm 11 not familiar with that term. 12 A. It entailed planning the 13 production of inventory for material that was 14 to be sold. Based upon inventory levels, we 15 would -- we would plan the raw materials that 16 needed to be brought in and then the 17 production schedules for the production of 18 the material. 19 Q. And so you're talking about raw 20 materials that would be, I guess, turned into 21 pharmaceuticals? 22 A. This is not pharmaceuticals at 23 that time. I was not in the 24 pharmaceutical -- I was in the specialty 25 chemical business, which was for raw</p>
<p style="text-align: right;">Page 19</p> <p>1 through the different positions that you've 2 held since starting at Mallinckrodt? 3 A. Sure, I'll try. 4 As I said, in 1976 I was hired 5 as a replacement for -- in customer service. 6 It was a business that no longer is with 7 Mallinckrodt. 8 And I eventually was hired full 9 time, and after about a year, that business 10 moved to Paris, Kentucky, and I stayed in 11 St. Louis and got a position in the 12 production and inventory control area in our 13 bulk business. 14 Q. Okay. And if I could pause you 15 there. 16 So when were you hired full 17 time, roughly what year? 18 A. It was in '76. 19 Q. And you were initially hired 20 into customer service for a business that 21 subsequently moved? 22 A. Right. 23 Q. A business line that 24 subsequently moved? 25 A. Right.</p>	<p style="text-align: right;">Page 21</p> <p>1 materials that went into food -- food -- 2 foods and industrial applications. This was 3 all down in our St. Louis plant. And this 4 was a raw material; it was not a finished 5 good. 6 Q. And so is it fair to say that 7 your job was to make sure that you had 8 sufficient amounts of the raw materials to 9 make the needed amounts of the finished 10 goods? 11 A. That was part of it, yes, to 12 make sure that the raw materials were 13 scheduled to be brought in on time so when we 14 were scheduling the run for making the 15 product that we wanted to make was there in 16 time. 17 Q. Okay. And how long did you 18 continue with those responsibilities? 19 A. I did that from 20 approximately -- well, I was a planner for 21 several years, and then I became a supervisor 22 over four or five planners, and I was in that 23 position until '91, and then I went to work 24 in customer service as a manager. 25 Q. And was that still related to</p>

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<p>1 raw chemicals in -- or was that in 2 pharmaceuticals?</p> <p>3 A. Yes, still -- I had the 4 acetaminophen, our acetaminophen customer 5 service group, I had our specialty chemical 6 group, and our bulk narcotic group reporting 7 to me.</p> <p>8 Q. Okay.</p> <p>9 A. And I reported into the sales 10 for the -- for the bulk area.</p> <p>11 Q. And what is -- what is the 12 specialty chemical group?</p> <p>13 A. Well, like I said, the 14 specialty chemical group is for raw materials 15 for us to produce finished good, raw 16 materials for, say, food applications. We 17 sold raw materials to Anheuser Busch. We 18 sold industrial chemicals, but they were all 19 raw material and then they would further take 20 our raw material and combine it with their 21 raw materials to make finished good or 22 whatever application they were using it for.</p> <p>23 Q. And none of these raw materials 24 related to the manufacture of opioids; is 25 that fair?</p>	<p>1 continued to be a raw material. That was 2 considered our finished good.</p> <p>3 Q. Okay.</p> <p>4 A. And was sold in bulk 5 quantities, hundred -- hundred kilos or 6 hundred pounds at a time.</p> <p>7 Q. So I just want to make sure 8 that I've got the timing correct.</p> <p>9 So in '91 you became a manager 10 and -- you became a manager of the 11 acetaminophen customer service group, the 12 specialty chemical group and the bulk 13 narcotic group; is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And did you -- did you later go 16 on other positions, or did you stay in that 17 position?</p> <p>18 A. Yes, I had that position until 19 approximately the fall of 2008, and then I 20 took over customer service for the dosage 21 business.</p> <p>22 Q. And can you describe for me 23 what the dosage business is?</p> <p>24 A. The dosage business is when you 25 take raw material products, opiate products,</p>
<p style="text-align: center;">Page 23</p> <p>1 A. That was another group. That 2 was our -- that was our bulk narcotic group.</p> <p>3 Q. Okay. And what -- can you 4 define for me, what is a bulk -- or what is a 5 bulk narcotic group?</p> <p>6 A. A bulk narcotic is a -- a raw 7 material that we produce from opiate and the 8 raw material is then sold to another 9 manufacturer who adds chemical -- other 10 chemicals to that -- our raw material to make 11 a finished product. Pills, powder, tablets.</p> <p>12 We did not make a finished 13 good, product, in the bulk area.</p> <p>14 Q. And the pills and powders and 15 tablets, that would later be sold to, for 16 example, distributors?</p> <p>17 A. Yes, from the manufacturers 18 that we sold to.</p> <p>19 Q. And when you say that you did 20 not make a finished good or a product, that's 21 with respect to the bulk narcotics; is that 22 correct?</p> <p>23 A. Correct. And when I say 24 "finished good," in your terms, it was not in 25 a tablet form or whatever. It was a --</p>	<p style="text-align: center;">Page 25</p> <p>1 and combine them with other chemicals to make 2 a finished good in the tablet or powder form.</p> <p>3 Q. So when you say you take raw 4 material products, this was Mallinckrodt raw 5 material products and making them into opioid 6 products?</p> <p>7 A. Yes.</p> <p>8 Q. And these opioid products would 9 subsequently be shipped out to Mallinckrodt's 10 customers; is that correct?</p> <p>11 A. Yes. Our distributor customers 12 and that, yes.</p> <p>13 Q. And you held this position from 14 2008 until you retired in 2012 -- or I'm 15 sorry, 2013?</p> <p>16 A. Correct.</p> <p>17 Q. Who was your predecessor in 18 this position -- I'm sorry, in this position?</p> <p>19 A. Cathy Stewart.</p> <p>20 Q. I know if I -- if I could go 21 back to the -- the bulk narcotics business 22 for a second.</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall who the 25 manufacturers were who purchased bulk</p>

Page 26	Page 28
<p>1 narcotics from Mallinckrodt?</p> <p>2 A. Oh, gosh. Purdue was one of</p> <p>3 the bigger ones. I don't remember -- I don't</p> <p>4 remember all of them.</p> <p>5 Q. Well, do you recall if Endo</p> <p>6 purchased any?</p> <p>7 A. Endo, I believe, was one of</p> <p>8 them, yes.</p> <p>9 Q. Okay. What about Teva?</p> <p>10 A. Yes.</p> <p>11 Q. What about Allergan?</p> <p>12 A. I believe so.</p> <p>13 Q. Okay. How about Johnson &</p> <p>14 Johnson?</p> <p>15 A. Yes.</p> <p>16 Q. How about Janssen?</p> <p>17 A. I believe so.</p> <p>18 Q. So in the context of the bulk</p> <p>19 narcotics business, you sold to most of the</p> <p>20 major manufacturers in the market; is that</p> <p>21 fair?</p> <p>22 A. Yes.</p> <p>23 Q. Sir, was your retirement</p> <p>24 voluntary?</p> <p>25 A. Yes.</p>	<p>1 customer-service-based compensation.</p> <p>2 Q. So do you recall in -- for</p> <p>3 2012, what was your base compensation?</p> <p>4 A. As far as dollars?</p> <p>5 Q. Yes.</p> <p>6 A. I don't remember.</p> <p>7 Q. And do you recall what your</p> <p>8 bonus was?</p> <p>9 A. Oh, my base as far as salary?</p> <p>10 Q. Yes, your base salary.</p> <p>11 A. It was probably around 90,000.</p> <p>12 Q. And then do you recall what</p> <p>13 your bonus was for that year?</p> <p>14 A. No. But it was like 10 percent</p> <p>15 was the -- was the most I could make, if I</p> <p>16 met my objectives.</p> <p>17 MR. TSAI: And, Dean, I know</p> <p>18 that the depo transcripts are</p> <p>19 presumptively highly confidential, but</p> <p>20 because you're getting into personal</p> <p>21 financial information, I do want to</p> <p>22 designate this discussion as highly</p> <p>23 confidential.</p> <p>24 MR. KAWAMOTO: Sure, that's</p> <p>25 fine.</p>
<p>1 Q. So you could have stayed on if</p> <p>2 you wanted to; you just decided it was time</p> <p>3 to go?</p> <p>4 A. Yes.</p> <p>5 Q. And can you briefly -- well,</p> <p>6 strike that.</p> <p>7 The position you held from fall</p> <p>8 of 2008 until 2013, what was your title?</p> <p>9 A. Manager of customer service.</p> <p>10 Q. And it was manager of customer</p> <p>11 service for dosage products, is that the</p> <p>12 full --</p> <p>13 A. Yes.</p> <p>14 Q. And what was your compen --</p> <p>15 well, what was your compensation scheme for</p> <p>16 your -- for your position?</p> <p>17 In other words, were you paid a</p> <p>18 base? Did you also have a bonus? How was</p> <p>19 that determined?</p> <p>20 A. At the time I reported into the</p> <p>21 logistics group, which included customer</p> <p>22 service, shipping and warehousing, and we did</p> <p>23 have a bonus that was based upon backorders,</p> <p>24 how long it took us to -- to answer the</p> <p>25 phone, that type of thing. Very</p>	<p>1 QUESTIONS BY MR. KAWAMOTO:</p> <p>2 Q. And the \$90,000, was this --</p> <p>3 was this more or less your base salary for</p> <p>4 the 2008 to 2013 time period?</p> <p>5 A. Well, we had yearly reviews,</p> <p>6 and based upon reviews and if you met your</p> <p>7 goals and that type of thing, depending on</p> <p>8 what the percentage was for that year, you</p> <p>9 know, it could go up or stay the same.</p> <p>10 Q. And were your reviews generally</p> <p>11 positive in your opinion?</p> <p>12 A. Yes. Yes.</p> <p>13 Q. Did anyone ever express any</p> <p>14 concerns about your performance?</p> <p>15 A. No.</p> <p>16 Q. And in terms of your goals,</p> <p>17 what are the goals that you recall that you</p> <p>18 were evaluated based on?</p> <p>19 A. I don't remember many of them.</p> <p>20 It's been a long time. But again, like I</p> <p>21 said, it was based upon, say, call answering</p> <p>22 rate, we needed to have it above 95 percent,</p> <p>23 so we would keep track of that, and that</p> <p>24 would be one goal.</p> <p>25 Keeping our backorders down to,</p>

<p style="text-align: right;">Page 30</p> <p>1 I forget what percentage, was another goal. 2 We had other goals as far as 3 having the CSRs attend -- or sign up for 4 different seminars, and we were responsible 5 for making sure that they met their goals 6 there. So that was another thing that we 7 were graded on.</p> <p>8 Just a few that I can think of.</p> <p>9 Q. Were any of these goals 10 compliance related?</p> <p>11 A. Karen Harper would have yearly, 12 if I remember right, a review of what was 13 going on in compliance and kind of keep us 14 abreast of any -- any new regulations or 15 anything like that that we may need to know 16 about.</p> <p>17 Q. And so was your compensation 18 based, in part, on your ability to comply 19 with these regulations?</p> <p>20 A. No.</p> <p>21 Q. And who reported to you?</p> <p>22 You were a manager, so who were 23 the people under you?</p> <p>24 A. I had five CSRs and one being a 25 lead.</p>	<p style="text-align: right;">Page 32</p> <p>1 there wasn't many because the DEA wanted to 2 keep control of where the production -- how 3 much production was being put out and who was 4 producing it.</p> <p>5 Q. So would you describe yourself 6 as one -- as essentially the dominant player 7 in the bulk narcotics business?</p> <p>8 A. I would say we were --</p> <p>9 MR. TSAI: Object to the form.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: -- we were one of 12 the larger producers.</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. And who were the other larger 15 producers in that space?</p> <p>16 A. Like I said, I don't remember.</p> <p>17 Q. Would you -- do you believe you 18 were the largest producer in that space?</p> <p>19 MR. TSAI: Objection. Vague as 20 to time.</p> <p>21 THE WITNESS: Yes, it depends 22 on the time frame that we're speaking.</p> <p>23 Early on we were probably one 24 of the largest ones. I'm not saying 25 we were the largest or not, I don't</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. Okay. And do you recall their 2 names?</p> <p>3 A. No, not all of them. Brenda 4 Raycop was the lead. I don't remember the 5 rest of their names.</p> <p>6 Q. And who did you report to?</p> <p>7 A. Well, at one time it was 8 Michael Pheney and George -- last one was 9 George -- I forget his last name now.</p> <p>10 Q. Is it George Saffold?</p> <p>11 A. Saffold, yes.</p> <p>12 Q. And you mentioned Karen Harper.</p> <p>13 A. Yes.</p> <p>14 Q. Did you report to her?</p> <p>15 A. No.</p> <p>16 Q. So going back to the bulk 17 narcotics business.</p> <p>18 Who would you say were your 19 main competitors in that field?</p> <p>20 A. Back then, we didn't have a 21 whole lot of competitors within the United 22 States. We had a -- we had a sizeable 23 percentage of the -- of the production that 24 the DEA allowed within the country. I don't 25 remember who they were, but it wasn't --</p>	<p style="text-align: right;">Page 33</p> <p>1 remember, but we were in the top 2 three, I would say.</p> <p>3 QUESTIONS BY MR. KAWAMOTO:</p> <p>4 Q. So, no, I understand that there 5 are limits to your memory.</p> <p>6 A. Right.</p> <p>7 Q. So what was the time frame 8 where you would -- where it would be fair to 9 say you were probably one of the largest?</p> <p>10 A. Well, like I said, I don't 11 remember.</p> <p>12 Q. Roughly would this be in the 13 2000s? In the '90s?</p> <p>14 A. Roughly, probably in the '90s 15 and early 2000.</p> <p>16 Q. And then I guess when you say 17 early 2000s, are we talking like 2005 to 18 2000 -- I'm sorry, 2000 to 2005 or 2006?</p> <p>19 A. 2000 to 2005 would be -- from 20 what I remember.</p> <p>21 Q. And then after 2005, you were 22 still a large producer; you just weren't the 23 largest; is that fair?</p> <p>24 A. That's true.</p> <p>25 Q. Now, focusing on your position</p>

<p style="text-align: right;">Page 34</p> <p>1 from 2008 to 2013, which is when you were the 2 customer service manager for dosage products. 3 A. Okay. 4 Q. What training did you receive 5 for your -- for that position? 6 A. Training was mostly done by the 7 previous customer service rep or manager, 8 Cathy Stewart. 9 Q. And do you recall what she did 10 to train you? 11 A. We just went over the processes 12 that the CSRs and that had to -- what was 13 needed as far as orders, forms needed from 14 the customers before we could ship orders 15 out, who their customers were, the product 16 line, that type of thing. 17 Q. And when you say "who their 18 customers were," were you -- are you 19 referring to Mallinckrodt's direct customers 20 or the customers of your customer? 21 A. Mallinckrodt's direct 22 customers. 23 Q. And when you say "product 24 line," what are you referring to? 25 A. This -- the products that we</p>	<p style="text-align: right;">Page 36</p> <p>1 office on a monthly basis. 2 Q. I'm sorry. 3 And roughly what time frame was 4 this process in effect for? 5 A. Probably 2000 -- and I'm 6 guessing because I don't remember exactly 7 when we started, when they requested this. 8 But I would say probably 2003, 9 '4 to 2006 or '7. 10 Q. And I take it the process then 11 changed in 2006 or '7? 12 A. That's -- that's correct. 13 Q. Okay. And what was that 14 different process then? 15 A. We started working on a more 16 enhanced suspicious order program at the 17 request of our compliance group to automate 18 it so we were capturing information on orders 19 at the time of -- the order was entered. It 20 was based upon a lot more detail than what we 21 had previously been supplying the DEA. The 22 DEA was in the process of changing what they 23 wanted to see and what they wanted to see 24 their customers, I'll call them, or the 25 registrants, what they wanted from them, from</p>
<p style="text-align: right;">Page 35</p> <p>1 sold in the finished good form. We're 2 talking about hydrocodone, oxycodone, 3 codeine, those type of products. 4 Q. And are you referring to 5 Mallinckrodt's generic products? 6 A. Yes. 7 Q. Okay. Would the product lines 8 you're responsible for also include 9 Mallinckrodt's branded products? 10 A. Yes. 11 Q. Now, are you familiar with the 12 term "suspicious order monitoring"?</p> <p>13 A. Yes, I am. 14 Q. What does that term mean to 15 you? 16 A. It was a process -- well, 17 depends on what time frame we're talking 18 about. When I was in the bulk business as a 19 customer service manager, when we first 20 developed the suspicious order monitoring 21 program requested by our St. Louis DEA, it 22 was a monthly report that we sent to them 23 showing orders that were out of the ordinary 24 as far as quantity or frequency, that type of 25 a report. It was sent to our DEA field</p>	<p style="text-align: right;">Page 37</p> <p>1 the registrants, and it became more complex 2 than what we had previously. 3 Q. And so I guess for simplicity's 4 sake, I will refer to the earlier suspicious 5 order monitoring program as the pre-2007 6 program, and then the enhanced one is either 7 the enhanced SOM or the post-2007; does that 8 make sense? 9 A. That's fine. 10 Q. Okay. So for the pre-2007 SOM 11 program, how did you identify the suspicious 12 orders? 13 A. It was -- the system -- it was 14 put into our order entry system and it was 15 based upon a log rhythm {sic} that we had 16 come up with and designed and was approved by 17 the DEA field office based upon the average 18 order quantity. And I believe it was 2 X was 19 the quantity that would flag an order on our 20 system -- 2 X meaning two times the normal 21 order pattern that the customer placed. And 22 it was a -- a running total. So it wasn't 23 just based upon a year. It was based upon 24 the previous 12 rolling months. 25 Q. And so just so I understand</p>

<p style="text-align: right;">Page 38</p> <p>1 sort of mathematically how this works, are 2 you essentially looking at the average over 3 the past 12 months and then seeing if the new 4 order is more than two times that average?</p> <p>5 A. That's correct.</p> <p>6 Q. Okay. So if the average -- I 7 understand that there may be different sort 8 of metrics, but if the average I had was, 9 let's say, 50 bottles per month --</p> <p>10 A. Correct.</p> <p>11 Q. -- that means that my new order 12 could be, I guess, up to a hundred bottles; 13 is that fair?</p> <p>14 A. Correct.</p> <p>15 Q. Okay.</p> <p>16 A. And keep in mind we not only 17 had the suspicious order monitoring program, 18 but the customers that we sold to also had to 19 supply quota forms and that, which was issued 20 by the DEA, on what they could buy. And 222 21 forms was another requirement giving -- that 22 had to be supplied with every order that they 23 placed.</p> <p>24 Q. And are they -- when you say 25 "quota forms," is that the same as the 222</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. And when you say it "had to 2 match," what does that mean?</p> <p>3 A. It couldn't be more than -- the 4 order couldn't be more than what was on the 5 222 form.</p> <p>6 Q. Okay.</p> <p>7 A. And the 222 form was -- was 8 received from the DEA.</p> <p>9 Q. And so the DEA would tell 10 the -- would tell the --</p> <p>11 A. Yes.</p> <p>12 Q. -- your customer how much they 13 could order on a monthly basis?</p> <p>14 A. I don't think it was on a 15 monthly basis. It was based -- I'm not sure. 16 I don't remember how the customer would get 17 their 222 form, but everybody in the quota 18 system -- the DEA would take -- the DEA would 19 take the total amount of a particular 20 product, like let's just say one product that 21 was sold in a particular year, and they would 22 look at that and that's the base of what we 23 are going to allow to be sold the following 24 year.</p> <p>25 Some customers, like</p>
<p style="text-align: right;">Page 39</p> <p>1 form?</p> <p>2 A. Quota forms were forms that 3 were used for raw material manufacturers.</p> <p>4 222 forms were used for 5 researchers and other type of registrants and 6 also for the dosage customers who were 7 ordering Schedule II products.</p> <p>8 Q. Okay. So you wouldn't need 9 both a quota form or a 22 form --</p> <p>10 A. Right.</p> <p>11 Q. -- or a 222 form.</p> <p>12 It was one or the other?</p> <p>13 A. Depending on their 14 registration.</p> <p>15 Q. And for the 222 form, what 16 would that tell you?</p> <p>17 A. Are we getting away from the 18 bulk side?</p> <p>19 Q. Yes, why don't we focus on 20 dosage and then we can come back to bulk.</p> <p>21 A. Okay.</p> <p>22 Q. Because the 222 form isn't used 23 in connection with bulk, correct?</p> <p>24 A. No, the 222 form had to match 25 the order that they were placing.</p>	<p style="text-align: right;">Page 41</p> <p>1 Mallinckrodt, would get a portion of that, 2 other manufacturers would get a portion of 3 that, and it was based upon their previous 4 sales. Okay. The same would be for the 5 distributors.</p> <p>6 And that's what they would 7 start off with for the year, how much they 8 could buy, and the way that they bought it 9 was with a 222 form, which the DEA would give 10 them these forms in advance and they had -- 11 they would, I guess, request more as they 12 needed them.</p> <p>13 Q. Okay.</p> <p>14 A. Just as long as it was within 15 their quota limits.</p> <p>16 Q. So it sounds like there are 17 essentially two quotas being imposed: 18 There's one being imposed on Mallinckrodt, 19 and then there's another one --</p> <p>20 A. As a manufacturer.</p> <p>21 Q. Yes, one being imposed on 22 Mallinckrodt as a manufacturer. Thank you.</p> <p>23 A. Right.</p> <p>24 Q. And one being imposed on 25 Mallinckrodt's customers, which it sounds</p>

<p style="text-align: right;">Page 42</p> <p>1 like are distributors?</p> <p>2 A. If you're looking at the bulk</p> <p>3 side, again, we're a bulk manufacturer and</p> <p>4 we're selling to bulk manufacturers who add,</p> <p>5 so they would buy it on their procurement</p> <p>6 quota, okay, so they would send us a quota</p> <p>7 form, too.</p> <p>8 Q. Okay. So is the only</p> <p>9 difference between a quota form and a 222</p> <p>10 form the nature of the customer submitting</p> <p>11 the form?</p> <p>12 A. It's the nature of their</p> <p>13 registration.</p> <p>14 Q. Okay. And so focusing on the</p> <p>15 dosage products, let's say I'm a distributor</p> <p>16 and the DEA has given me a quota of</p> <p>17 50 million pills, let's say, for the year.</p> <p>18 A. Okay.</p> <p>19 Q. And Mallinckrodt has a quota</p> <p>20 of, you know, 200 million pills.</p> <p>21 A. Okay.</p> <p>22 Q. I take it this means that my</p> <p>23 222 form that I submit to Mallinckrodt can't</p> <p>24 exceed 50 million; is that right?</p> <p>25 A. How much did you say they had?</p>	<p style="text-align: right;">Page 44</p> <p>1 the 222 form was likely going to</p> <p>2 significantly exceed any monthly order that</p> <p>3 the customer placed; is that fair?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. So it's not as if the</p> <p>6 222 form is really directly limiting the</p> <p>7 monthly order of a customer.</p> <p>8 The check on how much that</p> <p>9 customer can order on a monthly basis would</p> <p>10 be Mallinckrodt's algorithm?</p> <p>11 A. Yes.</p> <p>12 Q. And that algorithm for the</p> <p>13 2000 -- the pre-2007 time period was based on</p> <p>14 two times your yearly average -- I'm sorry,</p> <p>15 your yearly monthly average?</p> <p>16 A. Are we speaking on bulk?</p> <p>17 Q. No, I was talking about dosage</p> <p>18 products.</p> <p>19 A. Oh, okay.</p> <p>20 I'm not -- I didn't have it at</p> <p>21 that time. I believe they did have a similar</p> <p>22 report, but I'm not sure what the algorithm</p> <p>23 was at the time. That came under Cathy</p> <p>24 Stewart's watch.</p> <p>25 Q. But for the bulk products that</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Well, my overall quota is</p> <p>2 50 million.</p> <p>3 A. Right.</p> <p>4 Q. For the entire year, though.</p> <p>5 A. Right.</p> <p>6 Q. So when I submit a 222 form to</p> <p>7 Mallinckrodt, I mean, I assume so long as the</p> <p>8 number is not higher than 50 million, then</p> <p>9 it's okay?</p> <p>10 I'm trying to sort of</p> <p>11 understand what the -- what the limit is for</p> <p>12 the specific 222 form in any given month.</p> <p>13 A. Well, keep in mind that they</p> <p>14 wouldn't be bringing in 50 million tablets</p> <p>15 into their inventory. They didn't want to</p> <p>16 keep that kind of inventory. And that,</p> <p>17 again, would call fall under the suspicious</p> <p>18 order monitoring program, so that large of a</p> <p>19 quantity at one time would be brought to the</p> <p>20 attention of the DEA, and the DEA would look</p> <p>21 into why they're ordering so much at one</p> <p>22 time.</p> <p>23 Q. Understood.</p> <p>24 But as a general matter, the</p> <p>25 222 form -- well, the quota being applied to</p>	<p style="text-align: right;">Page 45</p> <p>1 you were in charge of --</p> <p>2 A. Uh-huh.</p> <p>3 Q. -- the algorithm was two times</p> <p>4 the monthly average?</p> <p>5 A. From what I remember, that's</p> <p>6 true.</p> <p>7 Q. Okay.</p> <p>8 A. Rolling average.</p> <p>9 Q. And I'm sorry, what's the</p> <p>10 difference between a rolling average and --</p> <p>11 A. It's not a calendar -- it's not</p> <p>12 a calendar period. It's a 12-month period.</p> <p>13 Q. Okay. So it's still 12 months.</p> <p>14 It's just you don't go from January to</p> <p>15 January.</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And so in the bulk</p> <p>18 context, if my monthly average was, let's</p> <p>19 say, 50 kilograms --</p> <p>20 A. Okay.</p> <p>21 Q. -- I could go up to a hundred</p> <p>22 kilograms on my next order?</p> <p>23 A. Correct.</p> <p>24 Q. And then, of course, if I order</p> <p>25 a hundred kilograms, that would affect my</p>

<p style="text-align: right;">Page 46</p> <p>1 average.</p> <p>2 A. Correct.</p> <p>3 Q. And so, you know, over -- over</p> <p>4 time, if you're using a two times algorithm,</p> <p>5 you know, the monthly limit on what you can</p> <p>6 order could increase significantly; isn't</p> <p>7 that fair?</p> <p>8 MR. TSAI: Object to the form.</p> <p>9 THE WITNESS: It could.</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. And was there any -- well, if</p> <p>12 you were to look at --</p> <p>13 A. But keep in mind --</p> <p>14 Q. Sorry, go ahead.</p> <p>15 A. But keep in mind, you know,</p> <p>16 they could increase their -- what they were</p> <p>17 ordering as long as it was within their quota</p> <p>18 from the DEA.</p> <p>19 Q. Understood.</p> <p>20 A. And then outside of our monthly</p> <p>21 report that went to the DEA, which the DEA</p> <p>22 was fine with, okay, with what we used for</p> <p>23 our criteria, we also -- the customer service</p> <p>24 reps were quite familiar with who our</p> <p>25 customers were and -- because there wasn't a</p>	<p style="text-align: right;">Page 48</p> <p>1 fair?</p> <p>2 A. That's true, yes.</p> <p>3 Q. Would you believe that there is</p> <p>4 an opioid -- that there's an opioid crisis in</p> <p>5 this country?</p> <p>6 A. That's what I have heard, yes.</p> <p>7 Q. And when you say that that's</p> <p>8 what you've heard, what do you mean by that?</p> <p>9 A. Well, on the news and that,</p> <p>10 I've heard that there's been an opioid</p> <p>11 epidemic, yes.</p> <p>12 Q. And you believe that's</p> <p>13 accurate?</p> <p>14 A. I can only, you know -- from</p> <p>15 what I've heard. I don't know personally.</p> <p>16 Q. But you don't have any reason</p> <p>17 to believe that that's -- that that's not</p> <p>18 true?</p> <p>19 A. No.</p> <p>20 Q. Do you believe that the drugs</p> <p>21 sold by Mallinckrodt contributed to this</p> <p>22 epidemic?</p> <p>23 A. That's a -- that's a -- no, I</p> <p>24 don't believe that, and why I say that is</p> <p>25 Mallinckrodt was -- was at the top of the --</p>
<p style="text-align: right;">Page 47</p> <p>1 huge number of bulk manufacturers that we</p> <p>2 were dealing with, like there wasn't new</p> <p>3 players all the time, so we had a pretty good</p> <p>4 understanding of what their needs were.</p> <p>5 So if there was something out</p> <p>6 of the ordinary that our CSRs saw, they would</p> <p>7 bring it to the attention of Karen Harper and</p> <p>8 just make her aware of it if she felt there</p> <p>9 was a need to look into it with the DEA or</p> <p>10 whatever.</p> <p>11 Q. And this is for the bulk</p> <p>12 narcotics process, correct?</p> <p>13 A. That's correct. That's what</p> <p>14 we're speaking to, yes.</p> <p>15 Q. And so in 2008, who took your</p> <p>16 place in -- with respect to bulk narcotics?</p> <p>17 Who assumed your position?</p> <p>18 A. Cathy Stewart. So we switched.</p> <p>19 Q. Okay. You switched.</p> <p>20 And do you recall who has or do</p> <p>21 you know who has your position now with</p> <p>22 respect to dosage products?</p> <p>23 A. No, I sure don't.</p> <p>24 Q. Okay. So, sir, you're aware</p> <p>25 that this case is about opioids; is that</p>	<p style="text-align: right;">Page 49</p> <p>1 what I'll call the chain in that we</p> <p>2 manufactured the product. We did not</p> <p>3 manufacture the -- we manufactured it, we</p> <p>4 shipped it, sold it to our distributors, the</p> <p>5 distributors sold it to the pharmacies, the</p> <p>6 pharmacies sold it to the physicians and the</p> <p>7 physicians sold it to -- or prescribed it to</p> <p>8 the patients. We were not in the position</p> <p>9 to, I guess, ever send the pills to an end</p> <p>10 user.</p> <p>11 Q. Well, when you say that there</p> <p>12 is an opioid epidemic, what's your</p> <p>13 understanding of the nature of the epidemic?</p> <p>14 A. I didn't say -- I agree with</p> <p>15 you that I believe that from what I've heard</p> <p>16 that there is.</p> <p>17 Q. Okay. So you've heard that --</p> <p>18 you've heard there's an opioid epidemic?</p> <p>19 A. Uh-huh.</p> <p>20 Q. What is your understanding of</p> <p>21 the nature of that epidemic?</p> <p>22 A. Well, it's from diversion of</p> <p>23 not only prescription medicine but from</p> <p>24 illegal products that are coming from other</p> <p>25 countries, that type of thing. It's not --</p>

<p style="text-align: right;">Page 50</p> <p>1 it's not all prescribed or prescription, 2 controlled medication. 3 Q. Would you agree that the 4 prescription controlled medication is a 5 significant component of this epidemic? 6 A. I -- from what I've read or 7 heard. 8 Q. And when you say "diversion," 9 what do you mean by that? 10 A. It's not being prescribed for 11 its intended use. 12 Q. And when you say "prescribed 13 for its intended use," what does that mean? 14 A. For medical purposes. For the 15 control -- what I consider medical use is 16 that the pills -- or the product that we sold 17 to other manufacturers who made a finished 18 good, intended use was for pain relief, okay, 19 and for people that were suffering from 20 long-term illness that needed pain relief, 21 cancer patients, surgery, people that had 22 surgery, that's what the intended use of the 23 opiates that we sold were for. 24 Q. And I'm just reading along -- 25 I'm just reading on the screen, but you</p>	<p style="text-align: right;">Page 52</p> <p>1 QUESTIONS BY MR. KAWAMOTO: 2 Q. Yes. 3 A. That's up to his doctor. 4 Q. Do you believe that opioids are 5 addictive? 6 A. I believe that they can be 7 addictive if they're abused. 8 Q. And do you believe that opioids 9 are being abused? 10 A. From my understanding and what 11 I've heard, yes, they can be abused. 12 Q. Okay. And what are the risk 13 factors for opioid abuse? Do you know what 14 any of them are? 15 A. I'm not familiar with it. 16 Q. Now, I just wanted to make sure 17 I understood your -- your understanding of 18 what the term "diversion" is. 19 But what -- could you define 20 "diversion" for me? 21 A. The way I think of diversion is 22 that the -- something that is being used 23 for -- is not being used for its intended use 24 I guess is the simplest way I can think of 25 it.</p>
<p style="text-align: right;">Page 51</p> <p>1 indicated that your understanding is that the 2 products being sold by Mallinckrodt were for 3 long-term illness that needed pain relief, 4 cancer patients and surgery, essentially 5 cancer pain or acute pain; is that fair? 6 A. Some of that, yeah. Some of 7 the major applications. 8 Q. Okay. Do you understand what 9 chronic pain is? 10 MR. TSAI: Objection to the 11 form. 12 Go ahead. 13 THE WITNESS: Chronic pain is 14 from -- what my understanding of it is 15 is for people that are constantly in 16 pain. Okay. I can say like my 17 brother-in-law who has a chronic pain 18 in his back, and it's just every day 19 is a hard time getting out of bed. 20 QUESTIONS BY MR. KAWAMOTO: 21 Q. And so in your opinion should 22 he be on opioids? 23 MR. TSAI: Object to the form. 24 Go ahead. 25 THE WITNESS: In my opinion?</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. And when you say "not being 2 used for its intended use," what do you mean 3 by that? 4 Are you talking about the 5 doctor is not appropriately prescribing it, 6 or what -- what do you mean by "not being 7 used for intended use"?</p> <p>8 A. I guess that that would be part 9 of it, yes, that the doctor is prescribing 10 maybe more than what the patient needs or 11 product is being brought over from other 12 countries, that type of thing. It's not for 13 its intended use as a medical need, I guess. 14 Q. So the fact that a patient is 15 taking an opioid pursuant to a prescription 16 doesn't necessarily mean that the patient is 17 not abusing opioids; is that fair? 18 A. Saying that again? 19 Q. The fact that a patient is 20 taking opioids pursuant to a prescription 21 from a doctor -- 22 A. Pursuant to a prescription. 23 Q. -- does not mean that the 24 patient -- well, strike that. Let me reask 25 that question.</p>

<p style="text-align: right;">Page 54</p> <p>1 A doctor could misprescribe 2 opioids; is that fair? 3 A. I guess they could. 4 Q. And you've indicated that would 5 be one example of diversion? 6 A. Yes. 7 Q. Okay. So if you had a patient 8 that was taking opioids pursuant to a 9 prescription that was improper, that patient 10 would be abusing opioids, notwithstanding the 11 fact they had a prescription? 12 MR. TSAI: Object to the form. 13 THE WITNESS: I guess -- I 14 guess that's possible. 15 QUESTIONS BY MR. KAWAMOTO: 16 Q. And so in terms of what the 17 problems are with diversion or what the harms 18 are with diversion, what in your opinion are 19 the problems or harms stemming from 20 diversion, the diversion of opioids? 21 MR. TSAI: Object to the form. 22 THE WITNESS: In my opinion as 23 a layman? 24 QUESTIONS BY MR. KAWAMOTO: 25 Q. Well, in your opinion as</p>	<p style="text-align: right;">Page 56</p> <p>1 the DEA changed their needs, our requirements 2 for us, I felt we had the controls in place 3 to meet that. 4 Q. Did others at Mallinckrodt ever 5 express any concerns to you regarding 6 diversion of Mallinckrodt products, opioid 7 products? 8 A. That there was a diversion 9 problem? 10 Q. That there either was a 11 diversion problem or that there was a risk of 12 Mallinckrodt products being diverted? 13 A. No. 14 MR. TSAI: Objection. 15 Compound. 16 Go ahead. 17 THE WITNESS: No, not that I 18 remember. Everybody -- everybody was 19 doing what they could in making sure 20 that we were meeting the needs of 21 the -- meeting the DEA compliance 22 needs. 23 QUESTIONS BY MR. KAWAMOTO: 24 Q. And did you understand 25 diversion to be an issue of corporate concern</p>
<p style="text-align: right;">Page 55</p> <p>1 someone that's worked for Mallinckrodt from 2 1976 to 2013 and spent the past -- well, the 3 past 12-plus years in their business. 4 A. Well, I would say if they 5 weren't using it for its intended use as a 6 medicinal pain reliever, then I guess it 7 could be abused. And if they abused it, they 8 could be -- become medically dependent on it. 9 Q. And so diversion, one of the 10 consequences of diversion, could be abuse and 11 addiction; is that fair? 12 A. Correct. 13 Q. Did you ever have any concerns 14 about diversion while you were working for 15 Mallinckrodt? 16 A. It was always a concern that we 17 have the proper tools in place to keep that 18 from happening, and I felt that we did with 19 the regulations that we filed -- that were 20 given to us by the DEA as far as needing the 21 222 forms, in the bulk side, the quota forms. 22 Also we had the necessary data collection 23 that the DEA asked us to submit to them, 24 which went from the monthly letters to a more 25 sophisticated reporting system. Later on as</p>	<p style="text-align: right;">Page 57</p> <p>1 for Mallinckrodt? 2 A. I believe it was a corporate 3 concern, and that's one of the reasons why 4 our controls were so -- so tight. 5 Q. And when you say your "controls 6 were so tight," what controls are you talking 7 about? Could you list them for me? 8 A. Well, what I mean by that is 9 what we've discussed already is that we were 10 meeting the compliance of the DEA regulations 11 with requiring the quota letters and the 222 12 forms, which were required, also the letter 13 that we -- and bulk, also on dosage, that we 14 were asked to submit on a monthly basis early 15 on. And then as the regulations -- or as the 16 DEA tightened their regulations and asked us 17 to submit more than just the letters and 18 actually end the letters and to come up with 19 a more robust -- more robust suspicious order 20 monitoring program, we did that going 21 forward. 22 I always felt that Mallinckrodt 23 was a -- felt that it was very important as a 24 citizen -- I'm calling Mallinckrodt as a 25 citizen -- to adhere and meet the needs of</p>

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<p>1 what the DEA was requiring over and beyond 2 anything. That was kind of our corporate 3 goal, I guess I would say.</p> <p>4 MR. TSAI: Dean, we've been 5 going about an hour.</p> <p>6 MR. KAWAMOTO: Sure, why don't 7 we take -- why don't we take a 8 ten-minute break.</p> <p>9 VIDEOGRAPHER: We're going off 10 the record at 10 a.m.</p> <p>11 (Off the record at 10:00 a.m.)</p> <p>12 VIDEOGRAPHER: We're back on 13 the record at 10:21 a.m.</p> <p>14 QUESTIONS BY MR. KAWAMOTO:</p> <p>15 Q. So, Mr. Rausch, you indicated 16 that in 2008 you and Cathy Stewart 17 essentially switched jobs.</p> <p>18 A. Yes.</p> <p>19 Q. So you went to dosage products, 20 and she went to bulk narcotics.</p> <p>21 A. That's correct.</p> <p>22 Q. Why did you switch?</p> <p>23 A. Our boss at the time, George 24 Saffold, wanted us to switch to learn more 25 about the other areas.</p>	<p>1 regulations that, like, Karen Harper in the 2 compliance group would be.</p> <p>3 But from what I remember, the 4 quota system was important in -- for the DEA 5 to keep track of what was being used in the 6 United States. So like I had mentioned 7 earlier, the DEA would take all the quota, 8 all the -- all the quota letters and forms 9 and the 222 forms that were used -- and I'm 10 not only talking, you know, from the 11 distributors but also from the pharmacists 12 and everyone else that had to report to the 13 DEA what they were using during the year -- 14 they would take that, add it all up and see 15 what the total was for United States for a 16 particular product. And they would use that 17 for their base for what they were going to 18 allow the following year. So that's why the 19 reporting through the quota system was very, 20 very important.</p> <p>21 Q. And you had indicated that the 22 compliance with the quota system was an 23 element of Mallinckrodt's efforts to fight 24 diversion; is that fair?</p> <p>25 A. Well, I wouldn't say it was</p>
<p>1 Q. And "the other areas" meaning 2 he wanted you to learn more about dosage 3 products and her to learn more about bulk 4 narcotics?</p> <p>5 A. That's correct, right.</p> <p>6 Q. Did George have any concerns 7 about Cathy's stewardship of the dosage 8 products?</p> <p>9 A. No.</p> <p>10 MR. TSAI: Object to the form.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. Okay. And would you view your 13 switch in 2008 as a promotion for you?</p> <p>14 A. No, it was a lateral.</p> <p>15 Q. Now, do you recall our prior 16 discussion regarding the quota system?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And so I want to focus 19 now on bulk narcotics with respect to the 20 quota system.</p> <p>21 Well, I guess why are quotas 22 important?</p> <p>23 A. Quotas are important -- and 24 again, I'm speaking as a customer service 25 person. I'm not, you know, privy to all the</p>	<p>1 that. You know, it was to meet the 2 regulations that were given to us by the DEA.</p> <p>3 As a good citizen, Mallinckrodt 4 being a good citizen, we felt it was very 5 important that we follow the regulations in 6 that to keep something like diversion from 7 happening.</p> <p>8 Q. And so what are -- what are all 9 of the steps -- focusing now on the bulk 10 narcotics side, what are all of the steps 11 that Mallinckrodt took to ensure that the 12 quota system was being complied with?</p> <p>13 A. We would -- we would require 14 from our customers, along with their order, 15 to send us a quota form under their license, 16 whether they're a manufacturer or a 17 researcher or whatever license they had, they 18 had to send us a quota form, and we would not 19 use -- we could not ship that order until 20 that form was sent to us. And what we would 21 do with the quota form is then turn that into 22 our compliance group.</p> <p>23 Q. And did the -- did the quota 24 form indicate their overall quota for the 25 year?</p>

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<p>1 A. No, usually it was the amount 2 that they were ordering. It couldn't be more 3 than what was on the order.</p> <p>4 Q. And so how -- how would 5 Mallinckrodt know that this order -- that the 6 order -- that the newest order your customer 7 had submitted didn't exceed their quota for 8 the year?</p> <p>9 A. It would show the total, I 10 believe, if I'm -- and I'm trying to 11 remember. I think it would show the total, 12 but then it would also show what they're 13 using for that particular order.</p> <p>14 Q. And when you say "total," I'm 15 sorry, what total are you referring to?</p> <p>16 A. You're asking what -- how we 17 knew what the customer's total was?</p> <p>18 Q. My apologies. So let me 19 rephrase that question.</p> <p>20 The quota form which showed the 21 total amount of that narcotic they had 22 received that year?</p> <p>23 A. That they were ordering from 24 us.</p> <p>25 Q. Okay. Understood. But I guess</p>	<p>1 Mallinckrodt, or was that all orders?</p> <p>2 A. It would be all orders.</p> <p>3 Q. Okay. So if Manufacturer A 4 were ordering, you know, bulk product from 5 Mallinckrodt and three other manufacturers, 6 the quota form is going to show the total 7 amount they had received from all of those 8 other manufacturers?</p> <p>9 A. Yes.</p> <p>10 Q. And did Mallinckrodt take any 11 steps to ensure that those numbers were 12 accurate?</p> <p>13 A. Customer service wasn't 14 responsible for that, so we would turn in the 15 forms to our -- to compliance groups, so that 16 would be for them to determine that. They 17 reported through their system, which was the 18 ARCOS system, which I'm not that familiar 19 with, but that's how they reported what the 20 manufacturer or our customers had taken from 21 us or sold to them from us.</p> <p>22 Q. And ARCOS would tell you how 23 much -- ARCOS would give you the amount of 24 product that the manufacturer had obtained 25 from Mallinckrodt.</p>
<p>1 my question may be a little different. 2 So let's say the DEA gives 3 Manufacturer A a quota of a hundred 4 kilograms?</p> <p>5 A. Uh-huh.</p> <p>6 Q. And Mallinckrodt -- and they 7 submit an order to Mallinckrodt asking to 8 purchase 3 kilograms.</p> <p>9 A. Okay.</p> <p>10 Q. How does Mallinckrodt know 11 that -- whether that 3-kilogram order is 12 going to exceed their hundred-kilogram quota?</p> <p>13 A. It would show the total and 14 then what had been used so far, from what I 15 remember.</p> <p>16 Q. So your recollection is that 17 the quota form is going to show their overall 18 quota, so a hundred kilograms?</p> <p>19 A. Right.</p> <p>20 Q. Plus the amount that they had 21 ordered up -- so the total amount they had 22 ordered thus far for the year?</p> <p>23 A. I believe so, from what I 24 remember.</p> <p>25 Q. And was that just orders for</p>	<p>1 Would it also provide you with 2 the information as to how much they had 3 obtained from everyone else?</p> <p>4 A. I would refer you to Karen 5 Harper on that.</p> <p>6 Q. And going over to the dosage 7 side, what was the system in place on the 8 dosage side to ensure that the quota system 9 was being complied with?</p> <p>10 A. The customer had to give us a 11 222 form that matched the order quantity that 12 they were ordering, and that 222 form would 13 then be sent to our compliance 14 person, and they would gather all that -- 15 those compliance forms, I believe, on a 16 monthly basis and send them to the DEA.</p> <p>17 But, again, that's the 18 compliance group, and I would refer you to 19 them for more information.</p> <p>20 Q. And did the 222 form also 21 contain the total quota assigned to that 22 distributor?</p> <p>23 A. No, I don't believe it did, 24 from what I remember. It was just for that 25 particular order.</p>

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<p>1 Q. So I guess going back to my 2 question from the bulk side. 3 A. Uh-huh. 4 Q. With respect to the dosage side 5 of the business, how did Mallinckrodt know 6 that -- well, strike that. 7 So let's take the following 8 hypothetical: Distributor A has a quota from 9 DEA for a hundred pills. 10 A. Uh-huh. 11 Q. It submits a 222 form to 12 Mallinckrodt asking to buy ten pills. 13 How does Mallinckrodt know that 14 those ten pills don't exceed the hundred-pill 15 quota? 16 A. We probably wouldn't, but 17 remember that the DEA is issuing the 222 18 form, so they -- as we turn in -- or we and 19 whoever else they're buying from -- the 222 20 forms back to the DEA, the DEA would give 21 them new 222 forms based upon what was left. 22 Q. And do you know how DEA set the 23 quotas? 24 A. No, that would be a Karen 25 Harper question.</p>	<p>1 being abused; is that fair? 2 A. Correct. 3 Q. Are you familiar with the term 4 "Ms"?' 5 A. Ms? 6 Q. Ms. 7 A. No, I'm not. 8 Q. Okay. What about "Mollies"?' 9 A. Mollies? 10 I've heard of them, but I don't 11 know specifically what they are. 12 Q. Okay. Are you familiar -- are 13 you familiar with any terms or any references 14 to Mallinckrodt products with respect to 15 being street drugs? 16 A. No. 17 Q. So given that Mallinckrodt 18 products were being diverted and they were 19 being abused, are there any additional steps, 20 looking back in hindsight, that you feel 21 Mallinckrodt should have taken? 22 A. Well, I just want to say that 23 if you remember where we were in the chain of 24 manufacturing, if we're talking about bulk at 25 this time -- are we talking about 2007? Are</p>
<p>1 Q. But you would agree that it's 2 very important to comply with that quota 3 system? 4 A. Oh, yes. 5 Q. So we previously spoke about 6 diversion. 7 Do you recall that? 8 A. Yes. 9 Q. And is it your understanding 10 that Mallinckrodt products were being 11 diverted? 12 A. Is it my understanding? 13 Not that I'm aware of. Just 14 from what -- I guess what I've heard from the 15 news. 16 Q. Well, but you've seen news 17 reports indicating that Mallinckrodt products 18 have been diverted; is that fair? 19 A. Yes. Yes. 20 Q. And do you recall what those 21 news reports said? 22 A. No, not really. 23 Q. But your understanding from 24 these news reports is that Mallinckrodt 25 products were being diverted and they were</p>	<p>1 we talking generic? What time frame? 2 Q. Let's start with dosage 3 products and then we can go to bulk. 4 A. Okay. Okay. 5 Keep in mind that the generic 6 business, we were -- you know, we had our own 7 regulations in place of meeting the DEA 8 requirements, plus we developed our 9 suspicious order monitoring program, which 10 was another step of identifying orders that 11 may have been out of order or suspicious 12 quantities. 13 And when we sold those, sold 14 our product, they went to distributors who 15 were supposed to have their own suspicious 16 order monitoring programs in place, and then 17 they sold to druggists and then to physicians 18 and then to the end user. 19 So there was a -- quite a 20 number of people in between Mallinckrodt and 21 the end user, so I would say that we did 22 our -- our due diligence in trying to keep 23 diversion from happening. 24 Q. And when you say "due 25 diligence," what do you mean by that?</p>

<p style="text-align: right;">Page 70</p> <p>1 A. By -- by meeting the 2 requirements of the DEA. 3 Q. And so it was very important to 4 you that Mallinckrodt meet these DEA 5 requirements? 6 A. I would say it's probably the 7 most important thing that we did. 8 Q. And this view was widely shared 9 at the company; is that correct? 10 A. Yes, it was. 11 I will add that when we were 12 developing our suspicious order program, that 13 that was rolled out to our marketing people 14 and also our sales force on what our 15 requirements were and what their part would 16 be going forward in helping us on -- on 17 controlling any -- any possible suspicious 18 orders or peculiar orders as we -- it became 19 known as later on. 20 Q. How did you know that your 21 suspicious order monitoring program was 22 effective? 23 A. We did not have one suspicious 24 order while I was doing the job. 25 Q. And when you say you did not</p>	<p style="text-align: right;">Page 72</p> <p>1 particular product that the order was for, 2 and I would ask them if they knew why all of 3 a sudden we were having a peculiar order from 4 that customer. 5 And a peculiar order, again, 6 would be unusual quantity from what they have 7 bought in the past over a period of time 8 based upon the log rhythms {sic} we set in 9 place in our computer system. 10 If they didn't know, my next 11 step would be going to the salesperson and 12 asking them. 13 Q. And so when you say that you 14 didn't have any suspicious orders, though, 15 what do you mean -- what do you mean by that? 16 A. Suspicious order is one that 17 would be -- where there is possible -- where 18 we could not identify for whatever -- what 19 reason the customer was ordering more than 20 what they had in the past. That would become 21 a suspicious order. And we report that to 22 Karen Harper and her group, who would then 23 report it to the DEA. 24 Q. And so I just want to make sure 25 I understand what your testimony is.</p>
<p style="text-align: right;">Page 71</p> <p>1 have one suspicious order while you were 2 doing the job, what do you mean by that? 3 A. Well, just to talk a little bit 4 about the suspicious order program that we 5 developed, an order would be flagged every 6 day -- an order could be flagged on a daily 7 basis as being suspicious or peculiar, as we 8 called it, and what that is, is just a stage 9 that we went through. 10 If an order was flagged as 11 being peculiar, it was during my time, my job 12 or responsibility to talk to marketing or our 13 customer service reps, who would be the first 14 people that I would talk to because they were 15 in tuned to our customers and what their 16 order needs were, and they would know if 17 there was anything unusual as far as a 18 distributor picking up a new customer that 19 they hadn't had before that they would now 20 need increased material to supply. 21 And if our CSR did not have 22 a -- an answer to why the customer was 23 ordering more, I would go to the product 24 manager, or business manager, whatever they 25 were being called at the time, who had that</p>	<p style="text-align: right;">Page 73</p> <p>1 Are you saying that because 2 none of your customers ever submitted a 3 suspicious order to you, that your suspicious 4 order monitoring program was effective? 5 MR. TSAI: Object to the form. 6 THE WITNESS: I'm saying that 7 during the time that I was running the 8 program and working the program that 9 we did not have a suspicious order. 10 QUESTIONS BY MR. KAWAMOTO: 11 Q. And when you say you "did not 12 have a suspicious order," that means that you 13 didn't identify any orders that were 14 suspicious? 15 A. We identified orders that were 16 peculiar, but we could explain them and did 17 not go to the point of being a suspicious 18 order. 19 Q. And I guess my question is, I 20 mean, you've indicated that you could explain 21 all of your peculiar orders. 22 How do you know that -- that 23 your explanations were, in fact, correct? 24 A. Because in identifying the -- 25 why the order was being determined being</p>

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<p>1 peculiar, we had a legitimate explanation of 2 why the order was larger or peculiar from 3 what it had been in the past, increased 4 sales, a new customer was coming aboard that 5 the customer of ours had gotten. They were 6 explainable orders is what I'm saying. So, 7 therefore, they went to peculiar order to 8 legitimate order.</p> <p>9 Q. And the explanation you were 10 getting, though, was ultimately being 11 provided by the customer; is that accurate?</p> <p>12 A. By the -- by the -- well, from 13 the salesman or from marketing or the product 14 manager in dealing with the customer.</p> <p>15 Q. So they would get the 16 information from the customer --</p> <p>17 A. Correct.</p> <p>18 Q. -- and relay it to you?</p> <p>19 A. At that -- yes.</p> <p>20 Q. Was there ever a circumstance 21 why a customer lied to one of your sales 22 reps?</p> <p>23 A. I don't know that.</p> <p>24 Q. If the customer lied to your 25 sales rep, then, in fact, the order would not</p>	<p>1 Q. Was the sales force's 2 compensation based upon their -- strike that. 3 Was the sales force's 4 compensation in any way based upon their 5 compliance with the DEA regulations?</p> <p>6 MR. TSAI: Object to the form.</p> <p>7 THE WITNESS: I can't -- I 8 can't answer that. I don't know.</p> <p>9 (Mallinckrodt-Rausch Exhibits 1 10 and 2 marked for identification.)</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. I would like to mark this as 13 Exhibit 1.</p> <p>14 And actually this Exhibit 1 15 goes in connection with Exhibit 2, so I'm 16 going to mark that as well.</p> <p>17 So. Mr. Rausch, I've handed 18 you two exhibits. The first one is an e-mail 19 chain and it bears the Bates number 20 MNK-T1_273559. That's Exhibit 1.</p> <p>21 And then I've also provided you 22 with an exhibit marked Exhibit 2. This is a 23 letter from the DEA, and it's dated 24 September 27, 2006, and it bears a Bates 25 number MNK-T1_273563.</p>
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<p>1 be legitimate; is that correct?</p> <p>2 MR. TSAI: Object to the form.</p> <p>3 Go ahead.</p> <p>4 THE WITNESS: That's possible, 5 but what I'm saying that from when I 6 was working at, we were -- we were 7 satisfied with explanations that we 8 were receiving from our sales force 9 and the marketing folks why the order 10 was legitimate.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. Are you familiar with the 13 compensation scheme for your sales force?</p> <p>14 A. No, I'm not.</p> <p>15 Q. Do you know if their bonus was 16 dependent in any way on the number of sales 17 they made?</p> <p>18 A. Well, I would guess that sales 19 would be involved, but keep in mind that the 20 sales force were very aware of the DEA 21 compliance that Mallinckrodt enforced and 22 they knew it could lead to firing or us 23 losing our license to manufacture and sell. 24 So it was a high priority for us over and 25 beyond sales.</p>	<p>1 A. Okay.</p> <p>2 Q. Do you have both exhibits, sir?</p> <p>3 A. I do.</p> <p>4 Q. So directing your attention to 5 the e-mail if the very top of the e-mail 6 chain?</p> <p>7 A. Which -- on Exhibit 1?</p> <p>8 Q. On Exhibit 1.</p> <p>9 A. Okay.</p> <p>10 Q. Do you see the second paragraph 11 that says, "Please note that Vince Kaiman and 12 I had a conversation"?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And this is an e-mail 15 from Karen Harper, but she's indicating that 16 she shared a DEA letter with you.</p> <p>17 Do you see that?</p> <p>18 A. Correct.</p> <p>19 Q. Okay. And Exhibit 2 I believe 20 is that letter.</p> <p>21 A. I want to look at that now?</p> <p>22 Q. Yes. Could you look at that?</p> <p>23 A. Okay.</p> <p>24 Q. Do you recall Karen Harper 25 sharing this letter from you -- with you?</p>

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<p>1 A. I don't. 2 Q. Okay. 3 A. Just because I don't remember 4 seeing it. It's been a long time. 5 Q. Sure. 6 But do you recall receiving 7 this letter at some point? 8 A. I don't recall it, but that 9 doesn't mean I didn't receive it. 10 Q. Okay. Do you recall ever 11 reviewing a letter like this? 12 A. Yes. 13 Q. And why did you review this 14 letter? 15 A. Can I -- 16 Q. Absolutely. 17 A. Can I take a look at it? 18 Q. Yes. Actually, why don't you 19 review that letter and let me know when 20 you're ready. 21 A. Okay. Okay. 22 Q. So directing your attention to 23 the second page of this letter, it bears the 24 Bates number 273564, do you see the third 25 paragraph from the bottom? It starts, "Thus</p>	<p>1 that the person placing the suspicious order 2 is a DEA registrant and turn a blind eye to 3 the suspicious circumstances." 4 Do you understand that to also 5 require -- also apply to Mallinckrodt as a 6 manufacturer? 7 A. Yes. 8 Q. Okay. Then turning to page 3 9 of the memo. It says, "Circumstances that 10 might be indicative of diversion." It 11 identifies four -- four circumstances. 12 Would you agree that those 13 circumstances are ones that are indicative of 14 diversion? 15 A. Certain pharmacies have engaged 16 in dispensing controls. 17 Those are four circumstances 18 that could lead to diversion, yes. 19 Q. And so if a distributor -- if a 20 distributor's order fell within one of these 21 four circumstances, you would agree that that 22 is potentially a suspicious order, would you 23 not? 24 A. Peculiar order, yes. 25 Q. Then below that, there's --</p>
<p style="text-align: center;">Page 79</p> <p>1 in addition." 2 A. Okay. 3 Q. And can you read that paragraph 4 into the record for me? 5 A. "Thus, in addition to reporting 6 all suspicious orders, a distributor has a 7 statutory responsibility to exercise due 8 diligence to avoid filling suspicious orders 9 that might be diverted into other than 10 legitimate, medical, scientific and 11 industrial channels. Failure to exercise 12 such due diligence could, as circumstances 13 warrant, provide a statutory -- statutory 14 basis for revocation or suspension of the 15 distributor's registration." 16 Q. Now, did you understand that 17 that legal requirement also applied to 18 Mallinckrodt as a manufacturer? 19 MR. TSAI: Object to the form. 20 Go ahead. 21 THE WITNESS: Yes. 22 QUESTIONS BY MR. KAWAMOTO: 23 Q. Okay. And then do you see in 24 the paragraph beneath that, it says, "A 25 distributor may not simply rely on the fact</p>	<p style="text-align: center;">Page 81</p> <p>1 there's a paragraph below that with ten 2 questions. 3 Do you see that? 4 A. Yes. 5 Q. So the first question is: 6 "What percentage of the pharmacy's business 7 does dispensing controlled substances 8 constitute?" 9 Would you agree that that is 10 important information to have and evaluate 11 whether an order is suspicious? 12 A. For the distributor? 13 Q. Yes. 14 A. I would say yes. 15 Q. And then if you were to change 16 this question so that it be what percentage 17 of the distributor's business does dispensing 18 controlled substances constitute, would you 19 agree that that's important information for 20 Mallinckrodt to have with respect to its 21 customer? 22 A. Yes. 23 Q. Okay. And so for number 2 it 24 says: "Is the pharmacy compliant with the 25 laws of every state in which it is dispensing</p>

<p style="text-align: right;">Page 82</p> <p>1 controlled substances?"</p> <p>2 If you were to substitute, you</p> <p>3 know, one of Mallinckrodt's customers in for</p> <p>4 "pharmacy," would you agree that's important</p> <p>5 information for Mallinckrodt to have?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. So looking at these -- I</p> <p>8 guess the remaining ten questions, in an</p> <p>9 effort to try to truncate things, would you</p> <p>10 agree that all of these questions, as applied</p> <p>11 to Mallinckrodt's customers, are important</p> <p>12 information for Mallinckrodt to have in</p> <p>13 assessing whether an order is peculiar?</p> <p>14 MR. TSAI: Object to the form.</p> <p>15 THE WITNESS: No, not all of</p> <p>16 them would apply to our business of</p> <p>17 selling to the distributors.</p> <p>18 QUESTIONS BY MR. KAWAMOTO:</p> <p>19 Q. Okay. Which ones would not</p> <p>20 apply?</p> <p>21 A. Well, does the pharmacy fill</p> <p>22 prescriptions issued by practitioners based</p> <p>23 solely on an online questionnaire without a</p> <p>24 medical exam or bona fide doctor-patient</p> <p>25 relationship.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And so if a pharmacy chain fell</p> <p>2 into any one of these six categories,</p> <p>3 wouldn't that be of concern to Mallinckrodt?</p> <p>4 MR. TSAI: Object to the form.</p> <p>5 THE WITNESS: I would guess so.</p> <p>6 QUESTIONS BY MR. KAWAMOTO:</p> <p>7 Q. Okay. So, for example, if you</p> <p>8 had a retail pharmacy that was soliciting</p> <p>9 buyers of controlled substances via the</p> <p>10 Internet or is a pharmacy associated with the</p> <p>11 Internet that solicits orders for controlled</p> <p>12 substances, that would be of concern to</p> <p>13 Mallinckrodt, would it not?</p> <p>14 A. Yes.</p> <p>15 Q. And modifying that question, if</p> <p>16 you were -- if one of your distributors was</p> <p>17 doing business with, for example, a pharmacy</p> <p>18 or an Internet site affiliated with the</p> <p>19 pharmacy offering to facilitate the</p> <p>20 acquisition of a prescription for a</p> <p>21 controlled substance from a practitioner with</p> <p>22 whom the buyer has no preexisting</p> <p>23 relationship, wouldn't that be of concern to</p> <p>24 you?</p> <p>25 A. We sold to the distributors,</p>
<p style="text-align: right;">Page 83</p> <p>1 Do you want me to go through</p> <p>2 all of them and tell you which ones I don't</p> <p>3 think would apply?</p> <p>4 Q. Yes, I think that would be</p> <p>5 helpful.</p> <p>6 So I have number 5 and then...</p> <p>7 A. Number 3.</p> <p>8 Q. Okay.</p> <p>9 A. Number 4.</p> <p>10 Number -- well, number 8 is</p> <p>11 something that we wouldn't -- wouldn't be</p> <p>12 part of.</p> <p>13 Number 9.</p> <p>14 Number 10.</p> <p>15 Q. And your basis for identifying</p> <p>16 these is because Mallinckrodt doesn't do</p> <p>17 business directly with pharmacies; is that</p> <p>18 correct?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. Does Mallinckrodt do</p> <p>21 business with retail pharmacies, though? For</p> <p>22 example, you know, CVS or Walgreens?</p> <p>23 A. With chains.</p> <p>24 Q. With pharmacy chains?</p> <p>25 A. Right.</p>	<p style="text-align: right;">Page 85</p> <p>1 not -- your question was about the</p> <p>2 distributor.</p> <p>3 Q. Well, no, I'm sorry. Let me</p> <p>4 rephrase that.</p> <p>5 My question is now about the</p> <p>6 distributors' customers.</p> <p>7 A. Okay.</p> <p>8 Q. So you've got a list here of</p> <p>9 ten essentially -- would it be fair to call</p> <p>10 these red flags?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. So you've got a</p> <p>13 question -- you've got a list here of ten red</p> <p>14 flags.</p> <p>15 If a distributor is doing</p> <p>16 business with a pharmacy that raises one or</p> <p>17 more red flags, wouldn't that be of concern</p> <p>18 to Mallinckrodt?</p> <p>19 MR. TSAI: Object to the form.</p> <p>20 THE WITNESS: Well, it would be</p> <p>21 a red flag for the distributor who</p> <p>22 also has a suspicious order monitoring</p> <p>23 program that should be in place.</p> <p>24 Okay.</p> <p>25 We were -- we were not</p>

<p style="text-align: right;">Page 86</p> <p>1 monitoring our customers' customer at 2 this time. We were asked to -- to 3 monitor our customers or build a 4 report -- a suspicious order program 5 on our customers.</p> <p>6 QUESTIONS BY MR. KAWAMOTO:</p> <p>7 Q. And you said you're not 8 monitoring them at this time.</p> <p>9 A. Well, okay. We weren't 10 monitoring them. When I had -- this is back 11 in 2007. When I was in -- or in 2006, 12 actually. When I didn't -- I was in the bulk 13 area, not in the dosage area.</p> <p>14 But our program was based upon 15 the customers that we were selling to, not 16 who our customers' customers were selling to. 17 We didn't have that information available to 18 us at that time.</p> <p>19 Q. And do you know if --</p> <p>20 A. Am I making myself clear?</p> <p>21 Q. Well, I think so, but I want to 22 make sure I understand what you're saying.</p> <p>23 A. Okay.</p> <p>24 Q. So with respect to the bulk 25 area, which is prior to 2007 -- which is</p>	<p style="text-align: right;">Page 88</p> <p>1 was put in place in the end of 2008. 2 So from the bulk business, we 3 were monitoring our customers, not their 4 customers.</p> <p>5 Q. But Mallinckrodt had the 6 capability of monitoring your customers' 7 customers, did it not?</p> <p>8 A. On the bulk business?</p> <p>9 No, not that I am aware of.</p> <p>10 Q. Did it have the ability to do 11 so on the dosage side?</p> <p>12 A. From a customer service 13 perspective, no.</p> <p>14 Q. Well, you indicated a customer 15 service perspective. I guess I would ask the 16 question --</p> <p>17 A. We did not have the resources 18 to identify who our customer -- who our 19 customer were selling to.</p> <p>20 Q. And when you say "resources," 21 you're talking about you didn't have enough 22 employees; you did not have enough staff?</p> <p>23 A. No, we didn't have the data 24 information available to us, that I'm aware 25 of.</p>
<p style="text-align: right;">Page 87</p> <p>1 prior to 2007 --</p> <p>2 A. Uh-huh.</p> <p>3 Q. This letter is dated 2006.</p> <p>4 You're saying that from -- from 5 the standpoint of the bulk narcotics 6 business --</p> <p>7 A. Yes.</p> <p>8 Q. -- you were not looking at your 9 customers' customer; is that accurate?</p> <p>10 A. That's correct.</p> <p>11 Q. Okay.</p> <p>12 A. And keep in mind, back then, we 13 were sending a monthly letter to the DEA 14 office, which I think I talked about earlier 15 in our conversation. That was the 16 requirement of the DEA at that time in 2006, 17 and I believe into 2007, and then the DEA was 18 telling us through our compliance group where 19 we were getting the information like this and 20 in talks with her that the letter was no 21 longer needed. They didn't want to see the 22 letter. They wanted us to start developing a 23 program, which we would call our -- ongoing 24 our suspicious order monitoring program, 25 which we worked on for a period of time and</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. On the -- either on the dosage 2 side or on the bulk side?</p> <p>3 A. Well, are we bouncing back and 4 forth?</p> <p>5 On the bulk side, we did not.</p> <p>6 Q. Okay. So on the bulk side, you 7 did not have -- you did not have the data 8 that would allow you to know who your 9 customers' customer was?</p> <p>10 A. Right.</p> <p>11 Q. Now, turning to the dosage 12 side --</p> <p>13 A. Which I did not have at that 14 time.</p> <p>15 Q. Understood.</p> <p>16 But turning to the dosage side 17 prior to 2007 --</p> <p>18 A. Right.</p> <p>19 Q. -- did Mallinckrodt -- are you 20 aware -- well, strike that.</p> <p>21 Did Mallinckrodt have the 22 ability to monitor its customers' customer?</p> <p>23 A. I was not aware if it was or 24 not.</p> <p>25 Q. And when you say you're "not</p>

<p style="text-align: right;">Page 90</p> <p>1 aware," is that -- strike that. 2 You don't know one way or the 3 other; is that fair? 4 A. Correct. 5 Q. Would Cathy Stewart know? 6 MR. TSAI: Object to the form. 7 THE WITNESS: I can't answer 8 that. I don't know what Cathy would 9 know about it.</p> <p>10 QUESTIONS BY MR. KAWAMOTO: 11 Q. Okay. But in any event, 12 Mallinckrodt was not monitoring its 13 customers' customer on the dosage side prior 14 to 2007? 15 A. As far as I know, they were 16 not. They were -- they were doing the same 17 thing the bulk side was doing. 18 Q. Would you agree, though, that 19 from a standpoint of diversion control and 20 diversion prevention, it would be helpful to 21 know your customers' customer? 22 A. I can't answer that. I 23 don't -- I don't know the answer to that from 24 a diversion. 25 I mean, keep in mind I want to</p>	<p style="text-align: right;">Page 92</p> <p>1 order there. We couldn't tell who they were 2 selling to at that time. 3 If you're asking me did I 4 think -- do I feel that knowing our 5 customers' customer would benefit 6 Mallinckrodt or benefit the diversion? It's 7 possible, but I can't answer that for sure. 8 Q. Well, if Mallinckrodt, though, 9 had the ability to monitor its customers' 10 customer, would you -- 11 A. Is that hypothetically? 12 Q. Hypothetically. 13 If they had the ability to do 14 that, would you agree that it would have been 15 helpful to diversion control for them to do 16 so? 17 MR. TSAI: Object to the form. 18 THE WITNESS: Yes, it would be 19 helpful. 20 QUESTIONS BY MR. KAWAMOTO: 21 Q. Okay. Do you believe it should 22 have been required? 23 A. I can't answer that. We were 24 meeting the requirements that I felt were in 25 place at the time.</p>
<p style="text-align: right;">Page 91</p> <p>1 reiterate that we were not the only player in 2 this -- in this closed loop where we were 3 selling to our customer, our customer was 4 supposed to be monitoring their customer all 5 the way down to the pharmacist and the 6 doctor. 7 Q. Well, but I have a slightly 8 different question, which is: You know a 9 distributor is distributing to, let's say, 10 Internet pharmacies that are just filling 11 prescriptions, you know, over the Internet, 12 it's soliciting orders over the Internet, and 13 that's an area of concern, that's one of the 14 red flags raised in this 2006 letter, is it 15 not? 16 A. Yes. 17 Q. Okay. So you've got a 18 distributor and you know that distributor is 19 doing business with those types of 20 pharmacies; isn't that of concern to 21 Mallinckrodt? 22 A. I think that's one of the 23 reasons we put in our program on the 24 deviation of orders that were coming from our 25 customers to show if there was a suspicious</p>	<p style="text-align: right;">Page 93</p> <p>1 That's a -- that's a Karen 2 Harper question. 3 Q. So turning now -- I'm going to 4 focus your attention on two other -- two more 5 exhibits, and so I'm marking these in tandem 6 as Exhibit 3 and as Exhibit 4. 7 (Mallinckrodt-Rausch Exhibits 3 8 and 4 marked for identification.) 9 QUESTIONS BY MR. KAWAMOTO: 10 Q. This is Exhibit 3 and it bears 11 the Bates number MNK-T1_419874. 12 And while I'm labeling things, 13 I'm going to also label Exhibit 4. This is a 14 DEA letter, and it bears a Bates number 15 MNK-T1_421084. 16 A. Okay. You want me to read 17 this, or you want just -- 18 Q. Actually, I just have a few 19 quick questions on this cover e-mail. 20 A. Okay. 21 Q. But it is an e-mail to -- from 22 Karen Harper to Cathy Stewart. 23 Do you see the second e-mail 24 that's dated -- the second e-mail from the 25 top dated March 12, 2008?</p>

<p style="text-align: right;">Page 94</p> <p>1 A. Okay. Yes.</p> <p>2 Q. It references attached</p> <p>3 information that Karen had sent to you and</p> <p>4 Michael Pheney.</p> <p>5 Who is Michael Pheney?</p> <p>6 A. Michael Pheney was my boss at</p> <p>7 the time.</p> <p>8 Q. And I believe the</p> <p>9 attachments on -- the attachment to this</p> <p>10 e-mail is this December 27, 2007 letter.</p> <p>11 So if I could -- well, do you</p> <p>12 recall Karen Harper sending you this -- this</p> <p>13 letter?</p> <p>14 A. No, I don't.</p> <p>15 Q. Okay. Actually, I'm sorry, if</p> <p>16 you look at the very bottom of the page,</p> <p>17 there's an e-mail from Karen Harper dated</p> <p>18 January 4, 2008, and you are -- you are one</p> <p>19 of the cc's.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Do you recall Karen</p> <p>23 Harper sending you this e-mail?</p> <p>24 A. No, it's been --</p> <p>25 Q. Do you have any reason to doubt</p>	<p style="text-align: right;">Page 96</p> <p>1 the responsibility does not end merely with</p> <p>2 the filing of a suspicious order report.</p> <p>3 Registrant must conduct an independent</p> <p>4 analysis of suspicious orders prior to</p> <p>5 completing a sale to determine whether the</p> <p>6 controlled substances are likely to be</p> <p>7 diverted from legitimate channels."</p> <p>8 Do you understand that</p> <p>9 language?</p> <p>10 A. Yes.</p> <p>11 Q. And is that -- is that a</p> <p>12 correct statement of Mallinckrodt's</p> <p>13 responsibilities under the law?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Further on down it</p> <p>16 states, "The regulation specifically states</p> <p>17 that suspicious orders include orders of an</p> <p>18 unusual size, orders deviating substantially</p> <p>19 from a normal pattern, and orders of an</p> <p>20 unusual frequency. These criteria are</p> <p>21 disjunctive and are not all inclusive."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And do you understand what that</p> <p>25 means?</p>
<p style="text-align: right;">Page 95</p> <p>1 that she sent you this e-mail?</p> <p>2 A. No, I don't.</p> <p>3 Q. Okay. Could you please review</p> <p>4 the December 27, 2007 letter? I believe</p> <p>5 that's Exhibit 4.</p> <p>6 A. Okay.</p> <p>7 Q. Okay. So do you recall</p> <p>8 reviewing this letter when you were employed</p> <p>9 by Mallinckrodt?</p> <p>10 A. I recall it.</p> <p>11 Q. Okay. So directing your</p> <p>12 attention to the third paragraph from the top</p> <p>13 of the first page of the letter --</p> <p>14 A. Okay.</p> <p>15 Q. -- it said, "The regulation</p> <p>16 also requires that the registrant inform the</p> <p>17 local DEA division office of suspicious</p> <p>18 orders when discovered by the registrant."</p> <p>19 A. Okay.</p> <p>20 Q. "Filing a monthly report of</p> <p>21 completed transactions, e.g., an excessive</p> <p>22 purchase report or high unit purchases, does</p> <p>23 not meet the regulatory requirement to report</p> <p>24 suspicious orders.</p> <p>25 Registrants are reminded that</p>	<p style="text-align: right;">Page 97</p> <p>1 A. Yes.</p> <p>2 Q. And is that an accurate</p> <p>3 statement of what a suspicious order is?</p> <p>4 A. Yes.</p> <p>5 Q. Okay.</p> <p>6 A. And then some.</p> <p>7 Q. Okay. At the very bottom of</p> <p>8 that paragraph it says, "The size of an order</p> <p>9 alone, whether or not it deviates from a</p> <p>10 normal pattern, is enough to trigger the</p> <p>11 registrant's responsibility to report the</p> <p>12 order as suspicious.</p> <p>13 "The determination of whether</p> <p>14 an order is suspicious depends not only on</p> <p>15 the ordering patterns of the particular</p> <p>16 customer but also on the patterns of the</p> <p>17 registrant's customer base and the patterns</p> <p>18 throughout the relevant segment of the</p> <p>19 regulated industry."</p> <p>20 Do you see that statement?</p> <p>21 A. I do.</p> <p>22 Q. And do you agree with it?</p> <p>23 A. Yes.</p> <p>24 Q. And so you understood this to</p> <p>25 be an accurate statement of Mallinckrodt's</p>

<p style="text-align: right;">Page 98</p> <p>1 legal responsibilities with respect to 2 suspicious orders? 3 A. From the bulk side, which is 4 where I was at this time, this was where we 5 started, from what I remember. Our St. Louis 6 field office did not want to receive the 7 monthly report any longer. Okay. 8 And we were instructed -- Karen 9 Harper and Michael Pheney and some other 10 folks put together a team of people to come 11 up with a more robust suspicious order 12 monitoring program, which included myself, 13 Cathy. Karen Harper oversaw it, but she 14 didn't come to all the meetings. We had a 15 few IT people that was involved, to come up 16 with a more robust ordering -- suspicious 17 order monitoring program that would identify 18 orders as being peculiar as the orders came 19 through. 20 This was developed over time 21 period of like 2000 -- in the 2000-2008 time 22 period and put in place. 23 Q. And this -- I guess you would 24 call -- 25 A. This was kind of the precursor</p>	<p style="text-align: right;">Page 100</p> <p>1 words, this was a floor, not a ceiling? 2 A. Correct. 3 Q. Okay. But it was -- it was 4 critically important to Mallinckrodt that its 5 enhanced SOM program meet, at a minimum, the 6 requirements in this letter? 7 A. Yes. 8 Q. Okay. And so directing your 9 attention to page 2, it says, "Registrants 10 that rely on rigid formulas to define whether 11 an order is suspicious may be failing to 12 detect suspicious orders. For example, a 13 system that identifies orders as suspicious 14 only if the total amount of a controlled 15 substance ordered during one month exceeds 16 the amount ordered the previous month by a 17 certain percentage or more is insufficient." 18 And so what is your 19 understanding of what that requirement is? 20 A. Well, I think what they're 21 saying is that it shouldn't be based on just 22 what the previous month was -- what -- what 23 previous month order might have been. Okay. 24 They're saying is that they 25 want you to take a look at an ongoing -- what</p>
<p style="text-align: right;">Page 99</p> <p>1 for that -- this kind of got the motion -- 2 wheels in motion for getting that done. 3 Q. So I take it -- and that's what 4 I think you previously referred to as your 5 enhanced suspicious order monitoring -- 6 A. Correct. 7 Q. -- program, your enhanced SOM 8 program? 9 A. Yes. 10 Q. And you would agree with me 11 that that enhanced program was required to 12 meet all of the requirements set forth in 13 this letter, would you not? 14 A. Not only what was in this 15 letter -- keep in mind the DEA did not tell 16 us what should be in our program. They 17 never -- they didn't tell us whether it was 18 correct. They didn't want to see a program. 19 They just told us that, "These are some of 20 the things that we wanted to see in your 21 program." 22 We did this stuff and included 23 some other things that they thought were 24 important. 25 Q. Okay. So this -- in other</p>	<p style="text-align: right;">Page 101</p> <p>1 I'll call a floating month period, like I 2 described earlier to you, a rolling time 3 period. So it wasn't from calendar year. It 4 was like January to January, February to 5 February, so it kept moving depending on -- 6 so if you were in April, it was looking at 7 orders that were placed from March to March, 8 okay. 9 Q. Now, it also says that 10 "Registrants that rely on rigid formulas to 11 define whether an order is suspicious may be 12 failing to detect suspicious orders." 13 A. That's exactly what I'm trying 14 to describe to you right there. They're not 15 saying don't look at what they ordered just 16 the previous month. Look at what they've 17 done over the previous 12 months or -- and in 18 our case, we said, okay, we're going to look 19 at a 12-month roving {sic} period of time. 20 Q. Okay. Doesn't this also tell 21 you though that if all you're doing is 22 relying on a rigid formula, on a numeric 23 formula, that is also insufficient? 24 MR. TSAI: Object to the form. 25 THE WITNESS: Yeah, and that's</p>

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<p>1 what I'm trying to explain to you. 2 Not only did we have this, what 3 they're saying -- they say ordered 4 during one-month period exceeds the 5 amount ordered, that was rigid, that's 6 what they considered rigid. Okay. 7 What they were saying, don't 8 rely on what they just ordered the 9 previous month, that's what they 10 considered rigid. 11 So the rolling months was not 12 rigid. Okay. 13 We only -- we not only did 14 rolling months, but we went in 15 frequency over a period of time. We 16 not only looked at a particular size, 17 and I'm -- of a bulk product, and this 18 also applies to the dosage because I'm 19 thinking of dosage. Because we had 20 different sizes of the same product. 21 We would look at the family, 22 okay, meaning combining all the 23 products within, let's say, 24 hydrocodone, we had several different 25 sizes. So we would look at the bulks</p>	<p>1 Indicative of Diversion." 2 I'm sorry, it's actually page 3 3 of the letter. 4 A. Okay. Page 3. 5 At the top? 6 Q. Yes. 7 A. Okay. 8 Q. You would agree that -- 9 A. Again, we're looking at 10 pharmacies, right? 11 Q. Well, we were looking at 12 "Circumstances that Might Be Indicative of 13 Diversion." 14 A. Okay. 15 Q. And so you would agree that an 16 adequate suspicious order monitoring program 17 would take into account these four 18 circumstances, would it not? 19 A. Number 2 I don't think is 20 something that would involve what we were in 21 the business of doing, ordering a limited 22 variety of controlled substances in 23 quantities disproportionate to the quantity 24 of noncontrolled medications. I -- I 25 don't -- I don't see how that applies to us.</p>
<p>1 of that size, okay. 2 So if they changed it up and 3 they went from a 10 by 50 to a 25 by 4 50, you know, just to -- we would -- 5 we would take the entire amount that 6 was being bought, make sure they 7 weren't buying more than what they 8 normally did. 9 So I think we did more so than 10 what the regulations were requiring. 11 QUESTIONS BY MR. KAWAMOTO: 12 Q. Now, directing your attention 13 back to Exhibit 2, do you have that in -- can 14 you put that in front of you so that -- yeah, 15 that would be the first DEA letter we looked 16 at. 17 A. Okay. 18 Q. And do you see on page 2, it's 19 got -- under the "Circumstances that Might Be 20 Indicative of Diversion," it's identifying 21 four different issues? 22 A. Page 2, you said? 23 Q. Yes. 24 A. And where at? 25 Q. "Circumstances that Might Be</p>	<p>1 Q. I'm sorry. 2 A. It's not something that we 3 would have been looking at. 4 Q. Well, isn't that what that -- 5 well, reading the requirement it says, 6 "Ordering a limited variety of controlled 7 substances in quantities disproportionate to the quantity 8 of noncontrolled medications ordered." 10 So if a distributor was doing 11 that from you, meaning all of the -- well, 12 let me rephrase that. 13 If a retail pharmacy was only 14 ordering controlled substances from you in 15 quantities disproportionate to the quantity 16 of noncontrolled medications ordered, so 17 we're talking a retail pharmacy here -- 18 A. Okay. 19 Q. -- wouldn't that be something 20 your suspicious order monitoring program 21 should pick up on? 22 A. When you say "noncontrolled 23 medication orders," I'm not sure, 24 noncontrolled medications, what would that 25 be?</p>

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<p>1 Q. Well, I assume it would be 2 other pharmaceuticals that were not, for 3 example, Schedule II. 4 A. Okay. 5 Again, I go back to this is 6 something that we were not -- we didn't have 7 the tools to do at that time. 8 Q. Well, but you would agree that 9 this is a circumstance that might be 10 indicative of diversion, would you not? 11 A. I suppose it could be, yes. 12 Q. And given that and given that 13 this is -- I mean, the DEA is flagging this 14 as an issue that they are concerned about, 15 wouldn't it be important for Mallinckrodt's 16 suspicious order monitoring program, 17 particularly its enhanced SOM program, to 18 take this into account? 19 A. We were -- as far as 20 pharmacies, we were selling to chain 21 pharmacies and we were shipping to -- to 22 their shipping sites, not particular 23 pharmacies. Okay. Not individual 24 pharmacies. We were selling to their 25 warehouses.</p>	<p>1 industrial channels may be failing to 2 maintain effective controls against 3 diversion." 4 Now, I guess to use the 5 Mallinckrodt terminology, I should be 6 substituting in "peculiar orders"; is that 7 fair? 8 A. Correct. 9 Q. Okay. So registrants that 10 routinely -- or, you know, registrants that 11 routinely report peculiar orders yet fill 12 those orders without first determining that 13 order is not being diverted into other than 14 legitimate, scientific and industrial 15 channels may be failing to maintain effective 16 controls against diversion. 17 You would agree with that 18 statement? 19 A. Yes. 20 Q. Okay. So as part of 21 Mallinckrodt's suspicious order monitoring 22 program -- 23 A. Yes. 24 Q. -- it had to make sure that it 25 did not report -- it did not identify</p>
<p>1 Q. But if a chain -- if a chain 2 pharmacy is only ordering Schedule II 3 substances from you, isn't that something 4 that your program ought to have taken into 5 account and registered? 6 A. If we had the resources to do 7 so, I suppose so. 8 MR. TSAI: Dean, this is a time 9 check. It's been about an hour since 10 the last break. 11 MR. KAWAMOTO: Sure. Actually, 12 why don't I finish up on Exhibit 4 and 13 then we can take a quick break. 14 QUESTIONS BY MR. KAWAMOTO: 15 Q. So page 2 of Exhibit 4, that's 16 the 2007 DEA letter. 17 A. Page -- okay. 18 Q. Page 2. 19 A. Of 4? 20 Q. Yes. 21 It says, "Lastly registrants 22 that routinely report suspicious orders yet 23 fill these orders without first determining 24 that order is not being diverted into other 25 than legitimate, medical, scientific and</p>	<p>1 Page 107 1 pecular orders and yet fill those orders 2 without first determining that the order was 3 not being diverted; is that correct? 4 A. Are you talking about -- at 5 this time period or are you talking during 6 when? Are we talking about bulk, or are we 7 talking about dosage? 8 Q. Well, let's focus on dosage 9 products. 10 A. Okay. 11 Q. And for dosage products -- 12 A. Right. 13 Q. -- prior to 2007, it would have 14 been improper for Mallinckrodt to identify a 15 pecular order and fill that order without 16 first determining that the order was not 17 being diverted into other than legitimate, 18 medical, scientific and industrial channels; 19 is that correct? 20 A. Yes. 21 Q. Okay. And presumably in the 22 post-2007 time period under your enhanced 23 suspicious order monitoring program, it still 24 would have been improper to fill an order 25 without first investigating the order; is</p>

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<p>1 that correct?</p> <p>2 MR. TSAI: Object to the form.</p> <p>3 THE WITNESS: Keep it in mind,</p> <p>4 like I've mentioned before, prior to</p> <p>5 2007, we were -- we were instructed by</p> <p>6 our field offices at that time, our</p> <p>7 DEA field offices, that the monthly</p> <p>8 report that we gave them was</p> <p>9 sufficient.</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. But nevertheless, from</p> <p>12 a -- from a standpoint of --</p> <p>13 A. From a -- from -- as far as --</p> <p>14 I can only speak towards bulk because that's</p> <p>15 what I had at the time. Okay.</p> <p>16 So besides the program that we</p> <p>17 had in place, which was what the DEA required</p> <p>18 at that time, regardless of what this letter</p> <p>19 is saying, we were also monitoring our</p> <p>20 customers of any orders that we felt -- our</p> <p>21 CSRs would notify myself or Karen Harper</p> <p>22 that, "Hey, we've got an order that's more --</p> <p>23 more than what the customer normally buys,"</p> <p>24 and we would -- we identify that and turn it</p> <p>25 over to Karen Harper for her -- to discuss</p>	<p>1 A. Yes.</p> <p>2 Q. So with respect to both bulk</p> <p>3 and dosage products, now, with respect to</p> <p>4 both pre-2007 and post-2007, it would have</p> <p>5 been improper for Mallinckrodt to ship an</p> <p>6 order without first concluding an</p> <p>7 investigation -- well, strike that.</p> <p>8 It would have been improper for</p> <p>9 Mallinckrodt to ship a peculiar order without</p> <p>10 first concluding its investigation as to</p> <p>11 whether that order was not going to be</p> <p>12 diverted; is that accurate?</p> <p>13 MR. TSAI: Object to the form.</p> <p>14 THE WITNESS: I would say that</p> <p>15 when I had dosage at the time, that we</p> <p>16 had an agreement with Karen Harper</p> <p>17 that we didn't always have the time</p> <p>18 because orders would go out on a daily</p> <p>19 basis from when they were -- they were</p> <p>20 entered, and they -- if an order</p> <p>21 kicked out as peculiar, we didn't</p> <p>22 always have the ability to do the</p> <p>23 thorough investigation prior to the</p> <p>24 order being shipped. Okay.</p> <p>25 And we came to that conclusion</p>
<p>1 with the DEA.</p> <p>2 I want to keep in mind that in</p> <p>3 the bulk area in a time frame of seven days</p> <p>4 to a month would be our normal period of</p> <p>5 fulfilling an order because we manufactured</p> <p>6 all the orders make-on-order. Okay. We</p> <p>7 didn't stock bulk narcotics. We didn't have</p> <p>8 the -- the inventory to be able to stock it,</p> <p>9 so everything was made to order. And the</p> <p>10 time frame that we needed our -- was anywhere</p> <p>11 from seven days to a month. Okay.</p> <p>12 So we had -- what I'm getting</p> <p>13 at is we had plenty of time prior to the</p> <p>14 order being shipped to determine whether it</p> <p>15 was suspicious order or not.</p> <p>16 Q. Okay. But as I -- as I</p> <p>17 understand this letter to be stating, and</p> <p>18 please correct me if you have a different</p> <p>19 interpretation, what it's saying is that if</p> <p>20 you identify a peculiar order, you should not</p> <p>21 ship that order without investigating whether</p> <p>22 the order is -- whether the order is being</p> <p>23 diverted; is that accurate?</p> <p>24 A. I would say so.</p> <p>25 Q. Okay.</p>	<p>1 after several months of orders being</p> <p>2 placed through our system and we did</p> <p>3 not have any suspicious orders. What</p> <p>4 we had -- had any suspicious orders,</p> <p>5 so we felt comfortable that we could</p> <p>6 go ahead and ship the order.</p> <p>7 And the reason why we were not</p> <p>8 able to always thoroughly investigate</p> <p>9 the order prior to it shipping was,</p> <p>10 one, we didn't have the information</p> <p>11 available from the CSR, our first</p> <p>12 contact, okay. They didn't know why</p> <p>13 this is -- this order is being placed</p> <p>14 for -- unusual order was being placed.</p> <p>15 Secondly, we would go to the</p> <p>16 business manager for that product. If</p> <p>17 that business manager didn't know why</p> <p>18 there was an unusual order being</p> <p>19 placed, we would then go to the</p> <p>20 salesperson. This all took time</p> <p>21 because these people aren't always</p> <p>22 available to get back to us. Okay.</p> <p>23 And we felt comfortable enough</p> <p>24 through our -- through this program</p> <p>25 being in place for several months</p>

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<p>1 before we went to that that we -- we 2 could continue to investigate that 3 order because that order was going to 4 a distributor who also had a program 5 in place for suspicious orders, so we 6 knew that we could get the product 7 back or stop it if need be.</p> <p>8 QUESTIONS BY MR. KAWAMOTO:</p> <p>9 Q. So in certain circumstances 10 then, Mallinckrodt would ship peculiar orders 11 without completing its investigation as to 12 whether that order might be diverted into 13 other than legitimate, medical, scientific or 14 industrial channels; is that correct?</p> <p>15 MR. TSAI: Objection. Vague as 16 to time.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: Yes, we -- on 19 rare circumstances where we didn't 20 want to hold up the order because of 21 people needing for legitimate reasons, 22 medical needs, we didn't want to hold 23 up the order, but we continued to go 24 through the process of identifying 25 whether it was legitimate or not.</p>	<p>1 without their blessing.</p> <p>2 Q. Did Karen Harper ever tell you 3 that the DEA had signed off on this 4 agreement?</p> <p>5 A. No.</p> <p>6 Q. Okay. And when you say that 7 you had an agreement with Karen Harper, what 8 do you mean by that?</p> <p>9 A. I asked her, based upon the 10 circumstances that I described, if it was 11 okay to do this, and she agreed to it.</p> <p>12 Q. Now, was this agreement 13 memorialized in writing?</p> <p>14 A. I believe there was an e-mail.</p> <p>15 Q. Okay. Was this agreement 16 memorialized in any formal policy put out by 17 Mallinckrodt?</p> <p>18 A. Not that I'm aware of.</p> <p>19 Q. So this agreement then would 20 not be included in whatever written policy 21 you had regarding your enhanced suspicious 22 order monitoring program, would it?</p> <p>23 A. I don't remember.</p> <p>24 MR. KAWAMOTO: Okay. Do you 25 want to take a break now, Rocky?</p>
<p>1 And I can say that from the 2 time period that I have it, we did not 3 have a suspicious order.</p> <p>4 QUESTIONS BY MR. KAWAMOTO:</p> <p>5 Q. Did you ever inform DEA that 6 you were doing this?</p> <p>7 A. Yes.</p> <p>8 Well, let me say we informed 9 our DEA compliance person, Karen Harper, and 10 she was in agreement to that.</p> <p>11 Q. But did you ever inform the 12 Drug Enforcement Administration?</p> <p>13 A. I did not talk to the Drug 14 Enforcement Agency myself.</p> <p>15 Q. Do you know if Karen Harper 16 informed the Drug Enforcement Administration?</p> <p>17 A. I don't know what Karen Harper 18 did.</p> <p>19 Q. So you have no basis to believe 20 that the DEA felt that this was an acceptable 21 practice?</p> <p>22 A. I would say, as well as I know 23 Karen Harper and how she dealt with the DEA, 24 she kept them informed of what we were doing. 25 She would not -- she would not do anything</p>	<p>1 Page 115</p> <p>1 MR. TSAI: Let's take a break, 2 yeah.</p> <p>3 VIDEOGRAPHER: We're going off 4 the record at 11:34 a.m.</p> <p>5 (Off the record at 11:34 a.m.)</p> <p>6 VIDEOGRAPHER: We're back on 7 the record at 11:49 a.m.</p> <p>8 QUESTIONS BY MR. KAWAMOTO:</p> <p>9 Q. So, Mr. Rausch, directing you 10 to Exhibit 4 again. It's a 2007 DEA letter.</p> <p>11 Do you have that in front of 12 you?</p> <p>13 A. Yes.</p> <p>14 Q. So looking on the back page on 15 the top paragraph -- and we've discussed this 16 briefly during the last session.</p> <p>17 A. Okay.</p> <p>18 Q. Do you see the top paragraph 19 where it says, "Registrants that rely on 20 rigid formulas to define whether an order is 21 suspicious may be failing to detect 22 suspicious orders."</p> <p>23 A. Yes.</p> <p>24 Q. And your interpretation of that 25 requirement is that you couldn't just rely on</p>

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<p>1 the month before; is that accurate?</p> <p>2 A. Well, I think that's what</p> <p>3 they're -- they're saying here. For example,</p> <p>4 a system that identifies orders as suspicious</p> <p>5 only if the total amount of controlled</p> <p>6 substance ordered during one month exceeds</p> <p>7 the amount ordered the previous month.</p> <p>8 Q. Okay. And so --</p> <p>9 A. That -- that I interpret as</p> <p>10 being rigid.</p> <p>11 Q. And so it would be improper to</p> <p>12 just look at one month, but if you were to</p> <p>13 look at the past two months, that would be</p> <p>14 okay; is that your interpretation?</p> <p>15 A. No. No.</p> <p>16 Well, what I'm saying is --</p> <p>17 what we -- what we did is we looked at a</p> <p>18 12-month roving {sic} period of time, as I</p> <p>19 explained earlier, where we not only looked</p> <p>20 at the previous month and the month before</p> <p>21 that and six months before that, but a year's</p> <p>22 basis.</p> <p>23 So if they placed an order, for</p> <p>24 example, in April, okay, what we looked at</p> <p>25 were orders that had been placed from, say,</p>	<p>1 interpretation?</p> <p>2 A. Just thought that was the</p> <p>3 better approach than just looking at one</p> <p>4 month.</p> <p>5 And if I'm reading here, it</p> <p>6 says, okay, "should not rely on rigid</p> <p>7 formulas to define whether an order is</p> <p>8 suspicious or not," and they give, for</p> <p>9 example, a system that defines -- identifies</p> <p>10 orders as suspicious only in a total amount</p> <p>11 of the controlled substance ordered during</p> <p>12 one month.</p> <p>13 Q. Well, let me -- go ahead.</p> <p>14 A. Do I understand what</p> <p>15 you're asking?</p> <p>16 Q. Well, let me phrase this</p> <p>17 another way.</p> <p>18 So you have three potential</p> <p>19 options. Option one is you would have -- you</p> <p>20 would base your SOM system on just look --</p> <p>21 just comparing the current order to the</p> <p>22 previous month's order, and your</p> <p>23 understanding is that the DEA disapproved of</p> <p>24 that approach.</p> <p>25 A. They show that as an example.</p>
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<p>1 March of that year, the month before, through</p> <p>2 the past March of the previous year.</p> <p>3 And so -- and that -- then that</p> <p>4 just kept changing. If an order was placed</p> <p>5 in May, we would look from April through</p> <p>6 April.</p> <p>7 Q. Okay.</p> <p>8 A. Does that make sense?</p> <p>9 Q. I believe I understand that.</p> <p>10 A. Okay.</p> <p>11 Q. I guess my question is so</p> <p>12 your -- your understanding of what it means</p> <p>13 not to rely on a rigid formula is that your</p> <p>14 formula shouldn't be time limited,</p> <p>15 essentially, to one month.</p> <p>16 Is that -- is that what you're</p> <p>17 indicating?</p> <p>18 A. I think that's what my -- our</p> <p>19 interpretation is what the DEA is saying</p> <p>20 there. Don't just look at one -- what they</p> <p>21 bought the previous month because that's not</p> <p>22 going to give you a good feel for an order</p> <p>23 pattern that is deviant from possibly past</p> <p>24 orders.</p> <p>25 Q. And what is your basis for that</p>	<p>1 Q. The other approach would be,</p> <p>2 you know, what you did -- what Mallinckrodt</p> <p>3 did, which is to compare the current order to</p> <p>4 the average of the past 12 months on a</p> <p>5 rolling basis; is that accurate?</p> <p>6 A. Correct. Correct.</p> <p>7 Q. Another approach would be in</p> <p>8 addition to looking at, you know -- in</p> <p>9 addition to comparing the current order to</p> <p>10 the prior 12-month order on a rolling basis,</p> <p>11 you could also look at other factors. For</p> <p>12 example, the factors identified in the 2006</p> <p>13 letter.</p> <p>14 So, you know, what are -- what</p> <p>15 are they ordering relative -- how much -- or</p> <p>16 how much opioids are they ordering relative</p> <p>17 to other products?</p> <p>18 Is there -- is there a pattern</p> <p>19 with respect to, you know, how often that</p> <p>20 they are -- they are providing an order that</p> <p>21 would, for example, trigger the peculiar</p> <p>22 order threshold?</p> <p>23 Are they ordering excessive</p> <p>24 quantities of controlled substances in</p> <p>25 combination with, you know, an excessive</p>

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<p>1 quantities of lifestyle drugs?</p> <p>2 So you could have a suspicious</p> <p>3 order monitoring program that had both this</p> <p>4 formula in addition to other factors.</p> <p>5 A. Well, keep in mind --</p> <p>6 MR. TSAI: Object to the form.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: Keep in mind that</p> <p>9 as the bulk customer service rep at</p> <p>10 that time, what the DEA -- our field</p> <p>11 office was requiring is what we were</p> <p>12 supplying. We gave them what -- what</p> <p>13 we had as our criteria, which I just</p> <p>14 told you it was based upon a 12-month</p> <p>15 rolling average. They approved that</p> <p>16 and we had that system in place up</p> <p>17 until 2007, 2008, at which time they</p> <p>18 said that was no longer going to be</p> <p>19 valid. And that's when we started</p> <p>20 developing our enhanced program.</p> <p>21 So regardless of what they have</p> <p>22 here, what our requirements were at</p> <p>23 the time was was what I just told you.</p> <p>24 QUESTIONS BY MR. KAWAMOTO:</p> <p>25 Q. And do you know -- is this the</p>	<p>1 was a particular size, like a 25-tablet</p> <p>2 bottle versus a 50-tablet bottle, they each</p> <p>3 would be separate SKUs. So just not looking</p> <p>4 at the orders for those particular ones. If</p> <p>5 they were within what we called the same</p> <p>6 family, we would look at the total of that</p> <p>7 family.</p> <p>8 So what we wanted to make sure</p> <p>9 as far as diversion is that to keep somebody</p> <p>10 from trying to get something by us is to one</p> <p>11 month order the 50-tab bottle and then the</p> <p>12 next month order the hundred-tab bottle. So</p> <p>13 we were looking at the combined of that</p> <p>14 family, combination of that family, and that</p> <p>15 would be flagged.</p> <p>16 Irregular order patterns was</p> <p>17 added, which I think is talked about in here.</p> <p>18 A number of different things.</p> <p>19 Q. And I'm sorry, when you were</p> <p>20 talking about the 50 versus a hundred tabs --</p> <p>21 A. Right.</p> <p>22 Q. -- what you're referring to</p> <p>23 is --</p> <p>24 A. Tablet bottles.</p> <p>25 Q. Tablet bottles.</p>
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<p>1 same system that was in place regarding</p> <p>2 dosage products for the prior -- the pre-2007</p> <p>3 time period?</p> <p>4 A. I believe so, but that's a</p> <p>5 question that I would refer to Cathy Stewart</p> <p>6 who had it at the same time.</p> <p>7 Q. Okay. And so if I understand</p> <p>8 your testimony, this formula, which was based</p> <p>9 on looking, comparing, the current order to</p> <p>10 the prior 12-month rolling period, that</p> <p>11 formula, was changed after 2007 when you took</p> <p>12 over the role of dosage products?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And what was -- what was</p> <p>15 the change or how was it changed?</p> <p>16 A. What was our new program?</p> <p>17 Q. Yes.</p> <p>18 A. Okay. I don't remember all of</p> <p>19 the particulars, but -- because it's been a</p> <p>20 long period of time.</p> <p>21 With the input of Cathy and</p> <p>22 several other people, it was based upon not</p> <p>23 only the order quantity on a rolling average,</p> <p>24 it was based upon not -- not only on a</p> <p>25 particular SKU, what I'll call a SKU, which</p>	<p>1 So ordering 50 tablet bottles</p> <p>2 from one family and then ordering a hundred</p> <p>3 tablet bottles from another family --</p> <p>4 A. No, from the same family.</p> <p>5 Okay.</p> <p>6 Q. Okay.</p> <p>7 A. So let's say hydrocodone,</p> <p>8 example, let's say they came in sized bottles</p> <p>9 of 50 tablets or a hundred tablets, okay, but</p> <p>10 they all came from the same crude, okay, or</p> <p>11 what we would call family, all right.</p> <p>12 So if somebody came in and</p> <p>13 ordered 100 one month, then came back the</p> <p>14 next month and ordered 50, the computer</p> <p>15 system would keep track of that and look at</p> <p>16 it at the higher level of where that was</p> <p>17 coming from in the crude. It would look at</p> <p>18 the total combination or combined of those</p> <p>19 orders.</p> <p>20 Q. So it was essentially looking</p> <p>21 at the number of -- it was taking into</p> <p>22 account the number of pills in the dosage --</p> <p>23 A. Correct.</p> <p>24 Q. -- as opposed to just --</p> <p>25 A. Correct.</p>

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<p>1 Q. -- you know, how many pills --</p> <p>2 A. Right.</p> <p>3 Q. -- or how many bottles?</p> <p>4 A. Right.</p> <p>5 Q. Okay. So why don't we turn</p> <p>6 to -- I would like to mark as -- I believe</p> <p>7 we're up to Exhibit 5.</p> <p>8 (Mallinckrodt-Rausch Exhibit 5</p> <p>9 marked for identification.)</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. And so I've marked as</p> <p>12 Exhibit 5, it's a PowerPoint. It's dated</p> <p>13 June 5, 2008. Because I've got it printed in</p> <p>14 native form, I'm going to read the Bates</p> <p>15 number into the record. So the Bates number</p> <p>16 for this is MNK-T1_2250046.</p> <p>17 So, Mr. Rausch, I would like</p> <p>18 you to quickly review this PowerPoint and let</p> <p>19 me know when you -- when you're done.</p> <p>20 A. Okay.</p> <p>21 Q. So this is a PowerPoint dated</p> <p>22 June 5, 2008, and its entitled "Introductory</p> <p>23 Training for Field Sales."</p> <p>24 Have you seen this PowerPoint</p> <p>25 before?</p>	<p>1 John Adams didn't.</p> <p>2 Karen Harper, I'm not sure if</p> <p>3 she did or didn't at that time. She -- her</p> <p>4 reporting relationship changed, but I don't</p> <p>5 remember what the time period was.</p> <p>6 Q. Okay. So at one time --</p> <p>7 A. Susan Marlatt didn't.</p> <p>8 Q. At one time she did report to</p> <p>9 JoAnne Levy or --</p> <p>10 A. I don't remember --</p> <p>11 Q. Okay.</p> <p>12 A. -- what her reporting</p> <p>13 relationship was at that time.</p> <p>14 Q. And so in terms of compliance</p> <p>15 issues, the people that would have been</p> <p>16 involved with the compliance side of the</p> <p>17 program -- well, could you identify for the</p> <p>18 people -- for me the people on this team that</p> <p>19 would have been involved in the compliance</p> <p>20 issues?</p> <p>21 A. Well, as far as customer</p> <p>22 service would be myself and Cathy. Susan</p> <p>23 Marlatt from the credit and collections</p> <p>24 department, they would be involved in setting</p> <p>25 up the customer and doing the credit</p>
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<p>1 A. I believe I have.</p> <p>2 Q. Okay. Did you help prepare</p> <p>3 this?</p> <p>4 A. No, it was prepared by Karen</p> <p>5 Harper, I believe.</p> <p>6 Q. Okay. But have you reviewed</p> <p>7 this before?</p> <p>8 A. I've seen it before.</p> <p>9 Q. And did you work with Karen</p> <p>10 Harper on preparing this?</p> <p>11 A. No, I don't believe so.</p> <p>12 Q. So turning to page 3 of the</p> <p>13 PowerPoint, it says, "Mallinckrodt's</p> <p>14 suspicious order procedure team."</p> <p>15 A. Oh, okay.</p> <p>16 Q. Do you see that page?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Who is JoAnne Levy or Levy?</p> <p>19 A. JoAnne Levy is the -- was the</p> <p>20 VP of logistics.</p> <p>21 Q. So did everyone else report up</p> <p>22 to her?</p> <p>23 A. No. Bill -- let's see.</p> <p>24 Michael Pheney did. I did.</p> <p>25 Cathy did. Bill Ratliff, I believe, did.</p>	<p>1 background checks on them.</p> <p>2 Who else we got?</p> <p>3 We all reported into -- well,</p> <p>4 not all. Cathy and myself reported into</p> <p>5 Michael Pheney.</p> <p>6 Kimberly France, I don't</p> <p>7 remember her.</p> <p>8 Q. And who was responsible for</p> <p>9 making sure that the program and the policies</p> <p>10 complied with the DEA regulations and</p> <p>11 applicable law?</p> <p>12 A. That would be Karen Harper.</p> <p>13 Q. Okay. Now, there are team</p> <p>14 advisors listed at the bottom of the page.</p> <p>15 A. Right.</p> <p>16 Q. Do you know what role they</p> <p>17 played?</p> <p>18 A. Their role was to enforce what</p> <p>19 the order monitoring procedures became --</p> <p>20 rolled out. They were at a higher level.</p> <p>21 This presentation was given and Jerry Moss</p> <p>22 was the vice president of sales for the bulk</p> <p>23 division, and Jason Jones, I'm not sure, but</p> <p>24 he was over one of the sales organizations.</p> <p>25 And same with Jeff Burd, he was marketing.</p>

<p style="text-align: right;">Page 130</p> <p>1 Bob Lesnak was in sales over the methadone 2 area, I believe, and then Eileen Spaulding, 3 was -- again, she reported into Karen Harper. 4 Q. And so you indicated that their 5 role was to enforce what the monitoring 6 procedure.</p> <p>7 So they -- did they help 8 develop them or -- sorry?</p> <p>9 A. Well, when I -- when you say 10 "enforce," to make sure that this was rolled 11 out to our salespeople.</p> <p>12 And what happened here, what 13 occurred, was every year the sales force 14 would get together for a week-long period of 15 time to go over different things that were 16 going on in sales and then something like 17 this would be rolled out by Karen during that 18 week --</p> <p>19 Q. Okay.</p> <p>20 A. -- just to instruct them on 21 what the new DEA regulations -- what the DEA 22 regulations were, what we were doing as far 23 as developing a new program, what their role 24 was expected of them in this program, and so 25 forth.</p>	<p style="text-align: right;">Page 132</p> <p>1 Q. And did someone take notes at 2 those meetings?</p> <p>3 A. I don't remember. I don't 4 remember.</p> <p>5 Q. Was there any type of secretary 6 for these meetings?</p> <p>7 A. No.</p> <p>8 Q. Did this team have any central 9 files?</p> <p>10 A. I don't remember.</p> <p>11 Most of the teams -- in this -- 12 I don't see -- let's see.</p> <p>13 Everybody was given assignments 14 on what was needed to be done and we work on 15 our assignments and meet on a frequent basis 16 to see where we were as far as coming up with 17 the new suspicious order reporting system.</p> <p>18 Q. And who was the team leader?</p> <p>19 A. I believe it was Karen.</p> <p>20 Q. So she would have been the one 21 giving out assignments and making sure that 22 they were completed; is that correct?</p> <p>23 A. Well, she wouldn't give out 24 assignments. During the meeting, we would 25 all talk about what we wanted to see, and</p>
<p style="text-align: right;">Page 131</p> <p>1 Q. And so the person that would 2 have been responsible for making sure that 3 the suspicious order monitoring program 4 complied with the DEA requirements was Karen 5 Harper?</p> <p>6 A. She would be the -- yes.</p> <p>7 Q. And so she would have been the 8 one that spoke to the DEA about this program?</p> <p>9 A. She probably tried -- yeah, she 10 would notify them, but the DEA did not say 11 one way or the other whether they liked it or 12 they didn't approve it or disapprove it. 13 They -- they stayed out of that.</p> <p>14 Q. Okay.</p> <p>15 A. As far as I remember.</p> <p>16 Q. Now, did --</p> <p>17 A. They didn't recommend a program 18 and didn't say whether -- or approve programs 19 as far as I know.</p> <p>20 Q. But if they had concerns, they 21 would let Mallinckrodt know, wouldn't they?</p> <p>22 A. Oh, yes. Yes.</p> <p>23 Q. Did this team have team 24 meetings?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 133</p> <p>1 based upon what person was involved in that 2 particular area, they would go back and work 3 on that.</p> <p>4 Say for IT, we asked them to 5 take a look at -- "IT" meaning information 6 services or computer people, okay -- we would 7 ask them to see, you know, can this be 8 implemented into the system, so they would go 9 back and do their due diligence on whether 10 that can be done.</p> <p>11 Cathy and I would be -- would 12 take a look at, you know, what was possible 13 on our end to get done.</p> <p>14 So everybody was given 15 assignments and then we would come back and 16 talk about what we had come up with or done.</p> <p>17 Q. And so -- well, strike that.</p> <p>18 Do you know when this team was 19 first formed?</p> <p>20 A. Not the exact time frame. This 21 was probably June of 2008. Probably earlier 22 in that time frame since we kind of details 23 out a little bit what we're going to be 24 looking at. Probably early 2008, maybe late 25 2007.</p>

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<p>1 Q. And was this team in existence 2 for your entire time between 2008 and 2013?</p> <p>3 A. No, this was just to roll out 4 our new order monitoring system. What -- 5 I -- I had control -- I had part of the 6 suspicious order monitoring program until 7 fall of 2010. Then it was turned over to 8 another group.</p> <p>9 Q. Okay.</p> <p>10 A. As far as being the one that 11 would follow up on peculiar orders and that.</p> <p>12 Q. And in fall of 2010, do you 13 know who it was turned over to?</p> <p>14 A. Tiffany -- I don't see her name 15 here. I do not remember her last name.</p> <p>16 Q. And was she in a different 17 group?</p> <p>18 A. She was.</p> <p>19 Q. What group was she in?</p> <p>20 A. I believe chargebacks.</p> <p>21 Q. So if you turn to the next 22 page, page 4, it says, "DEA policy on 23 suspicious orders."</p> <p>24 A. Okay.</p> <p>25 Q. And one of the bullet points</p>	<p>1 good feel who our customers were. We dealt 2 with them for years. And there wasn't that 3 many distributors in that that were -- or 4 drug manufacturers at that time. So we had a 5 pretty good idea of what their order patterns 6 were and that.</p> <p>7 And so if we felt something was 8 unusual or whatever, we would bring that up 9 to the business manager for the product 10 and/or the salesperson.</p> <p>11 Q. And when did you become -- when 12 did you -- when were you placed in charge of 13 the dosage products?</p> <p>14 A. 2008.</p> <p>15 Q. 2008.</p> <p>16 So --</p> <p>17 A. Fall of 2008, I believe.</p> <p>18 Q. So would have been after this 19 presentation, but --</p> <p>20 A. Yes.</p> <p>21 Q. A couple months after?</p> <p>22 A. Yes.</p> <p>23 Q. And so with respect to this 24 bullet point and your responsibilities on the 25 dosage side of Mallinckrodt's business, what</p>
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<p>1 is, "Registrant is reminded that the 2 responsibility does not end merely with the 3 filing of suspicious order report."</p> <p>4 A. Correct.</p> <p>5 Q. What does that mean to you?</p> <p>6 A. That's referring to the report 7 that we were sending on a monthly basis.</p> <p>8 Q. And so what are your additional 9 responsibilities other than filing -- well, 10 strike that.</p> <p>11 What are the responsibilities 12 you have after filing your suspicious order 13 report?</p> <p>14 A. Well, not only after filing it, 15 but during the interim, remember this was a 16 month-to-month report that we filed and it 17 was at the end of the month. So during a 18 month our -- our responsibilities were to 19 continue to look at the orders independent of 20 a report to see if there was unusual order 21 activity or -- or unusual orders being placed 22 that were out of the norm for that particular 23 customer.</p> <p>24 As I talked about earlier this 25 morning, on the bulk side, our CSRs had a</p>	<p>1 additional responsibilities did you have 2 other than filing the suspicious order 3 report?</p> <p>4 A. On the bulk side?</p> <p>5 Q. No, on the dosage side.</p> <p>6 A. Oh, at that time I did not have 7 any responsibilities. I'm sorry.</p> <p>8 Q. Well, this -- you've got a 9 bullet point here that says, "Registrant is 10 reminded that their responsibility does not 11 end merely with the filing of suspicious 12 order report."</p> <p>13 A. This is Cathy -- this would be 14 Cathy Stewart's responsibility.</p> <p>15 Q. Understood.</p> <p>16 But this requirement would also 17 have applied to you when you took over the 18 dosage side of the business, correct?</p> <p>19 A. After our -- after our new 20 reporting system was put in place.</p> <p>21 Q. So what additional 22 responsibilities -- after the new reporting 23 system gets put in place --</p> <p>24 A. Okay.</p> <p>25 Q. -- what additional</p>

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<p>1 responsibilities did you have other than 2 filing the suspicious order report? 3 A. We no longer file that report. 4 Our new monitoring system took the place of 5 that. The DEA didn't -- no longer wanted us 6 to send that report. 7 So during the time period of 8 2000 -- late 2008 and 2009, we worked on 9 our -- and this is discussed in this 10 presentation -- this team that was put 11 together worked on coming up with a new 12 report. 13 My responsibilities after it 14 was put in place was to receive the daily 15 reports, peculiar order reports, that flagged 16 the orders that were out of the log 17 rhythms {sic} of the normal order patterning. 18 Okay. 19 And my job, which I think I 20 kind of discussed earlier, was to -- the 21 orders that were flagged was to then talk to 22 the CSRs, the business managers, and the 23 sales force that were involved with this 24 particular customer that we were selling to 25 and trying to explain why the order pattern</p>	<p>1 of 2008 and the fall of 2009? 2 A. As I discussed, just our normal 3 DEA compliance with the 222 forms and that. 4 We were working on the process. 5 Other than the CSRs bringing up 6 a suspicious order based upon their 7 knowledge, we did not have a -- a suspicious 8 order program in place at that time as we 9 developed it. 10 Q. So in -- let's say we're 11 talking January of 2009 here. 12 A. Okay. 13 Q. A manufacturer -- I'm sorry, a 14 distributor for the dosage products submits 15 an order that is, say, more than two times 16 what it requested the prior month, that would 17 not have been flagged for further review or 18 investigation? 19 A. If the CSR noticed that it was 20 a larger order than normal based upon past 21 history, which we had on our computer, they 22 would bring it to the attention of -- of the 23 salesperson or the business manager for 24 approval to ship it. 25 Q. And was there a threshold that</p>
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<p>1 was not being followed or why this was an 2 unusual or peculiar order. 3 Q. And so -- well, so when did 4 this enhanced SOM policy become effective? 5 A. I believe it was in the fall 6 of 2009 is when we put it in place. This was 7 after -- after months of working on what we 8 wanted to see in the report. This is after 9 we tested -- put it in a test mode and ran it 10 parallel with our order entry system to see 11 if there was anything kicking out that 12 shouldn't been, and then we put it in what I 13 call live production. 14 Q. And so prior to 2009, what 15 policy and procedures were in place regarding 16 dosage products? 17 A. So just our normal due 18 diligence of the DEA requirements of making 19 sure that we had the 222 forms prior to the 20 order being shipped. All orders were placed 21 on hold prior to that form being received. 22 So that was our policy. 23 Q. And you -- did you have any 24 policy or process in place to identify 25 suspicious dosage orders between the fall</p>	<p>1 was being applied, or how was the CSR to know 2 that this was an unusual, large order? 3 A. Just from past order history 4 that was on the sales -- on the computer. 5 Q. And so any order that was 6 larger than the past sales history, or did it 7 have to be larger by a certain amount? 8 A. There wasn't a formal program 9 in process. As this -- as this suspicious 10 order thing points out, we were in the 11 process of coming up with a new program, so 12 from that standpoint, we didn't have a -- a 13 computer system that was doing it. It was 14 just informal. 15 Q. So I just want to make sure I 16 understand the chronology here. 17 So prior to 2008, for the 18 dosage products, what was the formula that 19 was applied to determine if there were -- if 20 an order was suspicious or not? 21 A. Prior to 2008, to my -- best of 22 my knowledge, because I was in the bulk area, 23 they were reporting the best -- or the same 24 way that I was, which was a monthly report. 25 Q. And that is they would look at</p>

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<p>1 the current month's report -- I'm sorry, they 2 would look at the current order and compare 3 it to the prior month?</p> <p>4 A. Rolling 12 months.</p> <p>5 Q. On a rolling 12-month basis. 6 And what was the threshold that 7 would trigger it being viewed as suspicious? 8 A. The average of that 12-month. 9 Two times that.</p> <p>10 Q. Two times that. 11 Okay. So prior to 2008, on the 12 dosage -- sorry.</p> <p>13 A. Let me -- let me qualify that. 14 I was not over that program at 15 the time. I was not in dosage, but I believe 16 that's what they were using, but I can't say 17 for sure. That question should be asked of 18 Cathy Stewart.</p> <p>19 Q. Understood. 20 But to the best of your 21 knowledge, prior to 2008, the formula that 22 was in place regarding dosage products was 23 that you looked at the current order and 24 compared it to the 12-month rolling average, 25 and if that order was more than two times the</p>	<p>1 had asked -- had asked you to discontinue 2 sending them the report. 3 But did they also tell you that 4 you didn't need to look at that data anymore? 5 A. I don't remember. 6 Q. But nevertheless, that -- that 7 formula was discontinued, and until fall 8 of 2009, nothing replaced it; is that 9 correct?</p> <p>10 MR. TSAI: Object to the form. 11 THE WITNESS: That's correct. 12 QUESTIONS BY MR. KAWAMOTO: 13 Q. So between the fall of 2008 and 14 the fall of 2009, your regulatory system 15 was -- well, strike that. 16 Between the fall of 2008 and 17 the fall of 2009, the only regulatory -- the 18 only regulatory requirement that you had in 19 place to guard against diversion for dosage 20 products was the 222 forms?</p> <p>21 MR. TSAI: Object to the form. 22 THE WITNESS: You say -- when 23 you say "only," it was the -- part of 24 the DEA requirement program that we 25 have 222 forms and quota forms</p>
<p style="text-align: center;">Page 143</p> <p>1 12-month rolling average, that would be 2 flagged as a peculiar order?</p> <p>3 A. I'm assuming that's what they 4 were doing.</p> <p>5 Q. Okay.</p> <p>6 A. That's what we did on the bulk 7 side.</p> <p>8 Q. And then in 2000 -- late 2008, 9 when you assumed control of the dosage 10 products --</p> <p>11 A. Uh-huh. After the -- after the 12 program was -- the new --</p> <p>13 Q. After the program was --</p> <p>14 A. Was put in place.</p> <p>15 Q. -- was put in place, but before 16 the new formula was developed, you didn't 17 have a formula in place at all?</p> <p>18 A. Correct.</p> <p>19 Q. So you just got rid of the -- 20 you no longer looked at the comparison 21 between the current order and the 12-month 22 rolling -- the two month -- I'm sorry?</p> <p>23 A. The DEA asked us to discontinue 24 sending them that letter.</p> <p>25 Q. Well, I understand that the DEA</p>	<p style="text-align: center;">Page 145</p> <p>1 required that, and to make -- to say 2 "only" kind of, I think, minimizes 3 or -- is playing it down that it was 4 not an important part of the DEA 5 regulations. We still had that 6 requirement.</p> <p>7 And keep in mind, we were -- we 8 were shipping to distributors who also 9 had requirements on having programs in 10 place. We were not shipping to the -- 11 the end users. There was many layers 12 of other players in this -- in this -- 13 I shouldn't say players, but other 14 people or companies that were involved 15 in the suspicious order process 16 besides Mallinckrodt.</p> <p>17 So to say, yes, we did not have 18 a program in place at the time. The 19 DEA was well aware that we did not 20 have a suspicious order program in 21 place. They asked us to put one in 22 place, and we kept them informed -- 23 and when I say "we," Karen Harper, 24 kept them informed -- on the progress 25 of developing the new program, and to</p>

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<p>1 my knowledge, they were fine with 2 that.</p> <p>3 QUESTIONS BY MR. KAWAMOTO:</p> <p>4 Q. But nevertheless, if you were 5 to compare January of 2008 with January 6 of 2009, the regulatory requirements in 7 effect on January of 2009 would be less than 8 the regulatory effects in January of -- than 9 the regulatory requirements for January 10 of 2008, that's correct?</p> <p>11 MR. TSAI: Object to the form.</p> <p>12 THE WITNESS: I would have to 13 agree, yes.</p> <p>14 QUESTIONS BY MR. KAWAMOTO:</p> <p>15 Q. Okay. Why was it important to 16 have -- strike that.</p> <p>17 With respect to the 18 pre-enhanced SOM program, you know -- well, 19 strike that.</p> <p>20 Why did Mallinckrodt have this 21 12-month rolling -- this [REDACTED] [REDACTED] in place?</p> <p>22 What was its purpose?</p> <p>23 A. The DEA asked us to report on a 24 monthly basis to them suspicious orders, what</p>	<p>1 MR. KAWAMOTO: Do you want to 2 come back at 1:15, 1:30?</p> <p>3 MR. TSAI: Let's do 45 minutes.</p> <p>4 Is that okay?</p> <p>5 THE WITNESS: Good.</p> <p>6 VIDEOGRAPHER: We're going off 7 the record at 12:28 p.m.</p> <p>8 (Off the record at 12:28 p.m.)</p> <p>9 VIDEOGRAPHER: We're back on 10 the record at 1:19 p.m.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. So, Mr. Rausch, in terms of the 13 bulk product side of the business, in 2007, 14 were you aware that Purdue pleaded guilty 15 with respect to its opioid business in 16 federal court?</p> <p>17 A. No, I'm not.</p> <p>18 Q. So were you aware that the 19 government was conducting an investigation 20 into Purdue?</p> <p>21 A. I don't remember that.</p> <p>22 Q. Okay. And you don't have any 23 knowledge or awareness or any recollection of 24 the fact that, for example, the Purdue 25 general counsel entered a guilty plea in</p>
<p>1 Page 147</p> <p>2 they called suspicious order, to develop a -- 3 a program, which I described to you, and to 4 send that to them on a monthly basis.</p> <p>5 Q. And this was in addition to the 6 222 form requirement, correct?</p> <p>7 A. The quota form, yes.</p> <p>8 Q. Yes.</p> <p>9 So why -- what was the benefit 10 of this added regulatory requirement given 11 that you had the quota form in place?</p> <p>12 A. I can't answer that. That's 13 a -- that's a question that you would have to 14 ask the DEA or Karen Harper.</p> <p>15 Q. But you would agree that this 16 was --</p> <p>17 A. This was what was asked of us. 18 We came up with a formula, and I think you 19 can even see the -- that we submitted to them 20 and they approved as far as the monthly 21 reporting basis, and that's what we went 22 with.</p> <p>23 MR. KAWAMOTO: Well, so it's 24 12:30 now, Rocky. Do you want to take 25 a break for lunch?</p> <p>MR. TSAI: That's okay.</p>	<p>1 connection with that investigation?</p> <p>2 A. I don't have recollection of 3 that, no.</p> <p>4 Q. Now, in terms of screening your 5 customers on the bulk side of the business, 6 is that information that you would take -- 7 you would have wanted to take into account in 8 determining whether or not to ship your 9 products to them?</p> <p>10 MR. TSAI: Object to the form.</p> <p>11 THE WITNESS: I would say, yes, 12 probably, it would be. Yes.</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. Okay.</p> <p>15 A. If they were -- if they were -- 16 was their license suspended; do you know?</p> <p>17 Q. I don't believe there was a 18 license suspension. I think it was a -- it 19 was a criminal indictment relating to 20 their -- to aspects of their business.</p> <p>21 A. Okay. Oh.</p> <p>22 And what was your question, 23 again?</p> <p>24 Q. Well, is this information -- in 25 terms of screening your customers -- well,</p>

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1 strike that. 2 You would agree that it is 3 important for Mallinckrodt to screen its 4 customers? 5 A. I agree. 6 Q. And part of that screening 7 should involve taking into account, you know, 8 whether they have any regulatory violations, 9 whether there are any pending investigations, 10 by the DOJ, the DOA or a state Attorney 11 General; is that fair? 12 A. We would continue to monitor 13 the orders that were being placed by them, 14 and if Karen Harper informed us that we were 15 not supposed to ship it to them anymore, even 16 though you mentioned that they did not have 17 their license suspended or whatever, I think 18 unless we were informed otherwise, we 19 probably would continue our order processing, 20 monitoring as it was then. 21 Q. So was the -- was the license 22 suspension the only reason Mallinckrodt would 23 stop shipping products to a customer? 24 A. I'm trying to think if there's 25 other reasons that I can think of offhand.	1 order monitoring, and it says, "Revision 2 number draft 3, published 6/02/2008." 3 A. Okay. 4 Q. So would this document have 5 been prepared in connection with the 6 suspicious order monitoring team and your 7 enhanced SOM? 8 A. Yes, it seems to be in the same 9 time period that we were working on it. 10 Q. Okay. And do you know if this 11 document was ever finalized? 12 A. I don't remember. 13 Q. Was there a written document 14 that memorialized Mallinckrodt's enhanced 15 suspicious order monitoring program? 16 A. I don't remember. 17 Q. So if I were to -- let's say in 18 2014, if I were to be hired by Mallinckrodt 19 to oversee its enhanced suspicious order 20 monitoring program with respect to dosage 21 products and I were to ask to see what the 22 policy was, what would you -- what would you 23 give to me? 24 MR. TSAI: Object to the form. 25 THE WITNESS: In 2014?
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1 If Karen wanted us to stop for 2 whatever reason, other than license 3 suspension, she would inform us to do so, and 4 I don't remember if she did or not. 5 Q. And do you have any -- do you 6 recall -- strike that. 7 Do you have any recollection of 8 Karen asking you to stop shipment for someone 9 for a reason other than a license suspension? 10 A. I don't recall. 11 (Mallinckrodt-Rausch Exhibit 6 12 marked for identification.) 13 QUESTIONS BY MR. KAWAMOTO: 14 Q. So I would like to mark this as 15 Exhibit 6. 16 And it is -- it bears the Bates 17 number MNK-T1_419993. It's Exhibit 6. 18 So, Mr. Rausch, have you seen 19 this document before? 20 A. I don't remember it. 21 Q. Okay. 22 A. That doesn't mean I didn't see 23 it, but I don't remember it. 24 Q. And this is a DEA compliance 25 procedure, controlled substance suspicious	1 QUESTIONS BY MR. KAWAMOTO: 2 Q. Yes. 3 A. I didn't work for the company 4 in 2014. 5 Q. Well, fair enough. 6 In 2013, if I'm coming in as 7 your replacement -- 8 A. Right. 9 Q. -- to oversee the dosage 10 products, and I ask -- and my responsibility 11 is to oversee -- 12 A. Right. 13 Q. -- the enhanced suspicious 14 order monitoring program, what document would 15 you have provided to me? 16 A. Most likely it would have a 17 document like this, because we did have -- we 18 did have documents for how things work at 19 customer service, and I am sure we had 20 something -- I would guess that we did have 21 something in place similar to this on what 22 customer service would do as far as the 23 procedure. 24 Q. Okay. So turning to page 2 of 25 this -- of this draft policy?

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	<p>1 A. Okay.</p> <p>2 Q. Do you see the section entitled</p> <p>3 "Credit Department"?</p> <p>4 A. I do.</p> <p>5 Q. And it says, "Performs Dun &</p> <p>6 Bradstreet and/or other information checks on</p> <p>7 new controlled substance customers to</p> <p>8 determine credit worthiness."</p> <p>9 Was this part of the enhanced</p> <p>10 SOM program for dosage products?</p> <p>11 A. I'm not -- I'm not sure if it's</p> <p>12 part of the enhanced. I'm not sure what the</p> <p>13 credit department did prior to this period of</p> <p>14 time, but I know they did -- they did check</p> <p>15 Dun & Bradstreet to -- prior to the new</p> <p>16 program.</p> <p>17 I would say the -- the part</p> <p>18 about referring the new customer account to</p> <p>19 the director of DEA compliance would be new,</p> <p>20 and the conducts periodic checks for existing</p> <p>21 accounts would also be new.</p> <p>22 Q. And I guess in terms of sort of</p> <p>23 overall what I'm trying to accomplish, I'm</p> <p>24 trying to understand whether or not these</p> <p>25 components made it into the final version of</p>	<p>1 A. Correct.</p> <p>2 Q. -- and presumably whether it</p> <p>3 would be able to pay any debts it owed to</p> <p>4 Mallinckrodt, correct?</p> <p>5 A. Correct.</p> <p>6 Q. Would this have helped prevent</p> <p>7 diversion in any way?</p> <p>8 A. No, I think this is -- this is</p> <p>9 just a -- part of the credit department's</p> <p>10 ongoing procedure.</p> <p>11 Like I said, it was probably</p> <p>12 two and three of this credit department that</p> <p>13 you have here that would be new to the</p> <p>14 compliance, SOM, suspicious order.</p> <p>15 Q. When you say "two or three,"</p> <p>16 what do you mean?</p> <p>17 A. Sentences two or three under</p> <p>18 the credit department.</p> <p>19 Q. Okay. So just so I'm clear,</p> <p>20 Dun & Bradstreet was not related to diversion</p> <p>21 control?</p> <p>22 A. No, that was always a -- a</p> <p>23 check that they did prior to -- to putting in</p> <p>24 a new customer.</p> <p>25 Q. Okay. And so Section 2 is --</p>
	<p style="text-align: center;">Page 155</p> <p>1 the enhanced SOM program.</p> <p>2 So with respect to the enhanced</p> <p>3 SOM program or the final version, would the</p> <p>4 credit department have performed a Dun &</p> <p>5 Bradstreet --</p> <p>6 A. Yes.</p> <p>7 Q. -- check?</p> <p>8 A. Yes.</p> <p>9 Q. Okay.</p> <p>10 A. I didn't work in that</p> <p>11 department, but I'm sure that that was part</p> <p>12 of their -- their process going forward.</p> <p>13 Q. And what was the purpose of</p> <p>14 performing that review or asking Dun &</p> <p>15 Bradstreet to perform that review?</p> <p>16 A. It would just give them a</p> <p>17 history of -- credit history of sales and</p> <p>18 that type of thing, if they had, you know,</p> <p>19 any debt or had gone bankrupt or that type of</p> <p>20 thing. I'm not speaking as a credit person,</p> <p>21 but I think that's what that was part of it.</p> <p>22 Q. So this would have addressed</p> <p>23 the concern -- I mean, the concern that</p> <p>24 Mallinckrodt had about the financial solvency</p> <p>25 of the institution --</p>	<p style="text-align: center;">Page 157</p> <p>1 refers to the new account customer DEA</p> <p>2 compliance of the new account has no</p> <p>3 historical or financial information available</p> <p>4 or if the data shows liens, lawsuits or other</p> <p>5 information which might raise suspicions to</p> <p>6 the legitimacy of the new account company.</p> <p>7 And how does that help</p> <p>8 prevent -- or how does that assist in</p> <p>9 diversion control?</p> <p>10 A. Well, again, you're speaking</p> <p>11 about an area that I was not part of, okay,</p> <p>12 so I can't answer that question. That's a</p> <p>13 credit department question.</p> <p>14 Q. And so the credit -- well, you</p> <p>15 indicated that part of your responsibilities</p> <p>16 was you identified -- part of your</p> <p>17 responsibilities under the enhanced SOM</p> <p>18 program is that you would identify peculiar</p> <p>19 orders or they would be identified to you on</p> <p>20 a report; is that fair?</p> <p>21 A. That's correct.</p> <p>22 Q. And then you would then take</p> <p>23 that order and interact with various people</p> <p>24 in the sales department to determine if there</p> <p>25 was a basis for that order; is that correct?</p>

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<p>1 A. Correct.</p> <p>2 Q. Did you ever interact with the</p> <p>3 credit department to determine if there was a</p> <p>4 basis for the order?</p> <p>5 A. This is referring to new</p> <p>6 customer accounts, okay. So the order would</p> <p>7 never -- there would never be an order placed</p> <p>8 unless the credit department established them</p> <p>9 as a -- as a new customer. Okay. So that</p> <p>10 would be preliminary work to me ever</p> <p>11 receiving an order.</p> <p>12 Q. And was there any effort made</p> <p>13 to update this information?</p> <p>14 A. There was a yearly -- there was</p> <p>15 a yearly form that was sent out by the credit</p> <p>16 department from what I can remember, that</p> <p>17 they had to -- it was a checklist that they</p> <p>18 had to fill out and send back to the credit</p> <p>19 department to keep their account current, and</p> <p>20 it had questions concerning the compliance</p> <p>21 that we were doing for the suspicious order</p> <p>22 monitoring program.</p> <p>23 This wasn't something new that</p> <p>24 was developed. I can't speak to what was all</p> <p>25 involved, but there was a yearly report or</p>	<p>1 the on-site visit and the photographs were?</p> <p>2 A. The reason for that is take a</p> <p>3 look at the physical property itself to see</p> <p>4 if it looked like a legitimate business.</p> <p>5 They didn't want it to be running out of</p> <p>6 somebody's house or whatever, so it had to be</p> <p>7 like, you know, physically have to look like</p> <p>8 there's a company that you would want to sell</p> <p>9 to and not being run out of back -- back of a</p> <p>10 hotel or something like that.</p> <p>11 So this information was passed</p> <p>12 on to the DEA director, I believe, is --</p> <p>13 yeah, it's security.</p> <p>14 Q. And your -- this requirement</p> <p>15 applies to Mallinckrodt's customers, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Would it be your expectation</p> <p>18 that the distributors would be doing</p> <p>19 something similar for their customers?</p> <p>20 A. I -- I can't answer that.</p> <p>21 Q. From a standpoint of diversion</p> <p>22 control, do you think it would be important</p> <p>23 for a distributor to do this?</p> <p>24 MS. YOCUM: Objection. Form.</p> <p>25 THE WITNESS: I can't speculate</p>
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<p>1 checklist that was sent out to the customer</p> <p>2 and they had to fill it out and send it back</p> <p>3 to them to keep them current as the customer.</p> <p>4 Q. Okay. And this was -- this was</p> <p>5 all being -- this was being done in</p> <p>6 connection with --</p> <p>7 A. Our enhanced reporting system</p> <p>8 and suspicious order reporting.</p> <p>9 Q. Okay. But credit didn't have</p> <p>10 any role in reviewing individual orders?</p> <p>11 A. No.</p> <p>12 Q. Okay. Now, the next section is</p> <p>13 on field sales.</p> <p>14 And by "field sales," I assume</p> <p>15 we're referring to the -- the salespeople in</p> <p>16 the field?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. It says, "Completes site</p> <p>19 survey checklist for new controlled substance</p> <p>20 customers," and then "conducts an on-site</p> <p>21 visit, including taking photographs inside</p> <p>22 and out for review by security director and</p> <p>23 DEA compliance manager."</p> <p>24 A. Uh-huh.</p> <p>25 Q. Do you know what the purpose of</p>	<p>1 on what they -- what we -- they would</p> <p>2 feel is important.</p> <p>3 Everybody had their own</p> <p>4 program, okay. We didn't have any</p> <p>5 guidelines from the DEA on what our</p> <p>6 program should look like.</p> <p>7 So as far as what the other</p> <p>8 companies or distributors did as far</p> <p>9 as their program, I don't -- I can't</p> <p>10 answer that.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. Well, I understand that you --</p> <p>13 sorry.</p> <p>14 A. Well, to answer that, you're</p> <p>15 asking me would I feel that that would be</p> <p>16 something that they would want to do?</p> <p>17 Q. Yes.</p> <p>18 A. I would say yes.</p> <p>19 Q. Now, for the customer service</p> <p>20 representatives, they break this up into bulk</p> <p>21 narcotics and dosage customer service reps.</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. And so you would have been</p> <p>25 responsible for the dosage customer service</p>

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<p>1 representative section; is that fair?</p> <p>2 A. At that time, I was -- fall</p> <p>3 of 2008.</p> <p>4 Q. Okay.</p> <p>5 A. So kind of in a transit year,</p> <p>6 but eventually, yes, I become manager --</p> <p>7 manager over the dosage area.</p> <p>8 Q. Okay. And on the top of --</p> <p>9 well, at the bottom of page 2 of 5 and going</p> <p>10 on to page 3 of 5, do you see, "Dosage</p> <p>11 customer service representatives will perform</p> <p>12 the following activities"?</p> <p>13 A. I'm sorry, which one am I</p> <p>14 supposed to be looking at?</p> <p>15 Q. At the bottom of page 2 of 5.</p> <p>16 So at the bottom of 41994. Under "Dosage</p> <p>17 Customer Service Representatives."</p> <p>18 A. Okay. Page 3?</p> <p>19 Q. Yes.</p> <p>20 A. Okay.</p> <p>21 Q. No, I'm sorry, page 2 of 5.</p> <p>22 A. Okay. Under the "bulk"</p> <p>23 section?</p> <p>24 Q. Under the "dosage." So beneath</p> <p>25 "bulk."</p>	<p>1 it says, "Need clarification."</p> <p>2 And again, this -- it does say</p> <p>3 draft, so this is a working document that was</p> <p>4 not the final document.</p> <p>5 Q. And so -- and that's part of</p> <p>6 why I'm asking these questions. I want to</p> <p>7 see if these -- if these responsibilities</p> <p>8 were transferred or were put into the final</p> <p>9 policy.</p> <p>10 A. Okay.</p> <p>11 Q. But the first one is, "Verify</p> <p>12 that the customer has a valid DEA</p> <p>13 registration certificate."</p> <p>14 I assume that was part of the</p> <p>15 final policy?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Then it also says,</p> <p>18 "Ensure that the customer has provided a</p> <p>19 properly executed DEA 222 form for C-I and</p> <p>20 C-II substances."</p> <p>21 A. Correct.</p> <p>22 Q. Was that part of the final</p> <p>23 policy?</p> <p>24 A. Yes.</p> <p>25 Q. Okay.</p>
<p style="text-align: center;">Page 163</p> <p>1 A. Okay. This is page 2.</p> <p>2 Q. Uh-huh.</p> <p>3 A. And this is page 3.</p> <p>4 Q. So page 2 would be this section</p> <p>5 right here.</p> <p>6 A. Oh, okay. Under --</p> <p>7 Q. So it says, "Dosage customer</p> <p>8 service representatives."</p> <p>9 A. Okay. Okay.</p> <p>10 Q. Okay. And it has -- it lists</p> <p>11 various requirements that start on page 2 and</p> <p>12 follow on to page 3.</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 I didn't -- I haven't read it</p> <p>16 yet, though.</p> <p>17 Q. Okay.</p> <p>18 A. Do you want me to read it?</p> <p>19 Q. Yes, please.</p> <p>20 A. Okay.</p> <p>21 This looks like a working</p> <p>22 document from what I can see, because I can</p> <p>23 see there's some -- there's some questions</p> <p>24 here where it says, "Dosage customer service</p> <p>25 will perform the following activities," and</p>	<p style="text-align: center;">Page 165</p> <p>1 A. That was part of our policy</p> <p>2 before the -- this program, but, yes, go</p> <p>3 ahead.</p> <p>4 Q. And then it also says, "Flag</p> <p>5 orders that deviate from the norms in terms</p> <p>6 of quantity order, frequency of order and/or</p> <p>7 pattern of normal order placement. CSRs will</p> <p>8 evaluate the circumstances of the order.</p> <p>9 This evaluation should be based on their</p> <p>10 knowledge of the specific customer and the</p> <p>11 industry in which the customer operates, and</p> <p>12 should the circumstances deviate from the</p> <p>13 norm, upon completion of the order, place</p> <p>14 same on hold and notify security and customer</p> <p>15 service manager."</p> <p>16 A. Okay.</p> <p>17 Q. Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Was that part of the final</p> <p>20 policy?</p> <p>21 A. That was part of our ongoing</p> <p>22 policy. Okay.</p> <p>23 So as I talked while we were --</p> <p>24 before where we were discussing what was --</p> <p>25 what took place, why we're developing our</p>

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<p>1 final policy, this is the type of thing --</p> <p>2 type of thing I was talking about where the</p> <p>3 CSR was, you know, knew the customer best and</p> <p>4 was to keep us informed if they saw something</p> <p>5 that was being ordered that was different</p> <p>6 from normal.</p> <p>7 Q. And how was the CSR to</p> <p>8 determine whether something was different</p> <p>9 from normal?</p> <p>10 A. Just from their knowledge of</p> <p>11 the customer, like I discussed earlier. Now,</p> <p>12 if they --</p> <p>13 Q. I'm sorry. Go ahead.</p> <p>14 A. Yeah, because this is referring</p> <p>15 not -- this is -- okay. This is -- we're</p> <p>16 looking at bulk here. Dosage is over here.</p> <p>17 Yeah, "This evaluation should</p> <p>18 be based on their knowledge of the specific</p> <p>19 customer and the industry in which the</p> <p>20 customer operates, and should the</p> <p>21 circumstances deviate from the norm, upon</p> <p>22 completion of the order, place same on hold</p> <p>23 and notify security," which would be Karen</p> <p>24 Harper's group, "and customer service</p> <p>25 manager."</p>	<p>1 A. I think there were five.</p> <p>2 Q. So you have five CSRs.</p> <p>3 A. Right.</p> <p>4 And they were -- they were</p> <p>5 responsible for particular customers.</p> <p>6 Q. Okay. And the CSRs were part</p> <p>7 of the sales team, were they not?</p> <p>8 A. No. They reported into</p> <p>9 logistics.</p> <p>10 Q. Yeah.</p> <p>11 And so how were the CSRs</p> <p>12 compensated?</p> <p>13 A. They weren't under the bonus</p> <p>14 program. They just had a salary.</p> <p>15 Q. So they didn't have a bonus</p> <p>16 program; it was just a salary?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And in terms of the</p> <p>19 factors that a CSR was to consider in</p> <p>20 determining whether an order was peculiar,</p> <p>21 was there a list of factors?</p> <p>22 A. I'm sorry, say that again.</p> <p>23 Q. Let me rephrase that question.</p> <p>24 So as I understand it, the CSR</p> <p>25 had the ability to flag an order that he or</p>
<p style="text-align: center;">Page 167</p> <p>1 Q. And so was this --</p> <p>2 A. That was in place while we were</p> <p>3 developing our program, and also as -- as we</p> <p>4 went on, our program would kick out these</p> <p>5 orders, so the CSRs still had the chance, as</p> <p>6 they were placing the order, to say, "Hey,</p> <p>7 something's wrong here," and bring it to the</p> <p>8 attention of the customer service manager or</p> <p>9 the DEA compliance officer, but we also had</p> <p>10 our program in place that would flag orders</p> <p>11 that were considered peculiar.</p> <p>12 Q. And that program in place to</p> <p>13 flag orders, that was what was activated in</p> <p>14 the fall of 2009?</p> <p>15 A. That's correct.</p> <p>16 Q. So with respect to the ability</p> <p>17 of the CSR to identify orders that they think</p> <p>18 are peculiar, were there standards they were</p> <p>19 supposed to apply in that respect?</p> <p>20 A. Just -- just orders that</p> <p>21 were -- seemed out of place to them.</p> <p>22 Q. Okay.</p> <p>23 A. As far as I remember.</p> <p>24 Q. And how many different CSRs did</p> <p>25 you have?</p>	<p style="text-align: center;">Page 169</p> <p>1 she believed was peculiar or unusual; is that</p> <p>2 fair?</p> <p>3 A. For that customer, yes.</p> <p>4 Q. Okay. And in terms of</p> <p>5 assessing whether an order was peculiar or</p> <p>6 unusual, was there a set of -- was there a</p> <p>7 written standard that they were supposed to</p> <p>8 apply or a set of factors they were supposed</p> <p>9 to look to?</p> <p>10 A. Just past order history for</p> <p>11 that customer, and then they would talk to --</p> <p>12 bring it to my attention or to the business</p> <p>13 manager and ask them if they knew why this</p> <p>14 particular order was different from what</p> <p>15 their normal order pattern was, and then</p> <p>16 if -- go ahead.</p> <p>17 Q. And in terms of past order</p> <p>18 history, what we're talking about is just</p> <p>19 looking at whatever -- whatever they had --</p> <p>20 whatever they had ordered previously?</p> <p>21 A. Correct.</p> <p>22 Q. And was there any threshold</p> <p>23 that was applied in terms of, you know, an</p> <p>24 order X percentage above the prior history</p> <p>25 would be viewed as peculiar, or was it really</p>

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<p>1 left up to the CSR?</p> <p>2 A. I don't remember, to be honest</p> <p>3 with you, what -- what we gave them as</p> <p>4 parameters, whether it was an X factor or if</p> <p>5 it's just based upon their -- their knowledge</p> <p>6 and the order history during this time period</p> <p>7 while we were developing our suspicious order</p> <p>8 program.</p> <p>9 Q. And did you have any program in</p> <p>10 place to audit the CSRs to make sure that</p> <p>11 they were -- they were accurately picking up</p> <p>12 on suspicious orders?</p> <p>13 A. Not that I remember.</p> <p>14 Q. Were CSRs evaluated on their</p> <p>15 ability to properly identify suspicious</p> <p>16 orders?</p> <p>17 A. Were they evaluated?</p> <p>18 Q. Well, let me -- let me rephrase</p> <p>19 that question.</p> <p>20 The CSRs were subject to an</p> <p>21 annual review process, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Was part of this annual review</p> <p>24 process a review of, you know, whether they</p> <p>25 accurately identified suspicious orders?</p>	<p>1 by the DEA?</p> <p>2 A. If they did -- and I don't want</p> <p>3 to say I remember that any particular one</p> <p>4 was, but I believe that there was, but I</p> <p>5 couldn't tell you who it was, and if it was</p> <p>6 the DEA would notify us and then we would no</p> <p>7 longer sell to them. But I can't say yes or</p> <p>8 no for sure that there was a -- a distributor</p> <p>9 who was -- had their license suspended.</p> <p>10 Q. Well, based on your -- your</p> <p>11 reading or your viewing of news reports, are</p> <p>12 you aware of distributors that appear to have</p> <p>13 been abusing the system?</p> <p>14 A. In 2008?</p> <p>15 Q. Well, in 2008 up till 2017.</p> <p>16 A. I think there was, yes.</p> <p>17 Q. Okay. And, you know, is it</p> <p>18 fair to say that these distributors were not</p> <p>19 properly applying whatever standards they</p> <p>20 were supposed to prevent diversion?</p> <p>21 MS. YOCUM: Objection. Form.</p> <p>22 QUESTIONS BY MR. KAWAMOTO:</p> <p>23 Q. So you can answer.</p> <p>24 A. Oh, okay.</p> <p>25 That's -- that's speculation on</p>
<p style="text-align: center;">Page 171</p> <p>1 MR. TSAI: Object to the form.</p> <p>2 THE WITNESS: Not that I</p> <p>3 remember.</p> <p>4 QUESTIONS BY MR. KAWAMOTO:</p> <p>5 Q. So do you have any way of</p> <p>6 ascertaining whether or not the CSRs</p> <p>7 successfully identified suspicious orders?</p> <p>8 A. Well, I just -- I just want to</p> <p>9 point out not only were our customer service</p> <p>10 reps and Mallinckrodt responsible for</p> <p>11 identifying suspicious orders, but also the</p> <p>12 people that we sold to, which were the</p> <p>13 distributors, and the distributors to the</p> <p>14 pharmacies all were responsible for doing</p> <p>15 this.</p> <p>16 So as far as diversion and that</p> <p>17 type of thing, there was -- there was a long</p> <p>18 list of people in between us and the customer</p> <p>19 or the end user.</p> <p>20 Q. Mallinckrodt had a number of</p> <p>21 different distributors that it did business</p> <p>22 with, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. Do you know if any of these</p> <p>25 distributors ever had their licenses revoked</p>	<p style="text-align: center;">Page 173</p> <p>1 my point. I don't know.</p> <p>2 Q. Was it consistent with your</p> <p>3 understanding of Mallinckrodt's</p> <p>4 responsibilities with respect to the DEA</p> <p>5 rules and regulations that Mallinckrodt could</p> <p>6 rely on the distributors to do their job to</p> <p>7 stop diversion, or were you independently</p> <p>8 responsible for preventing suspicious orders?</p> <p>9 A. I believe that we were</p> <p>10 responsible for monitoring our customers and</p> <p>11 that's what we were working on at the time.</p> <p>12 Q. And so if your customers were</p> <p>13 improperly distributing Mallinckrodt</p> <p>14 products, then these Mallinckrodt products</p> <p>15 would contribute to the diversion crisis,</p> <p>16 wouldn't they?</p> <p>17 MR. TSAI: Object to the form.</p> <p>18 MS. YOCUM: Object to the form.</p> <p>19 THE WITNESS: That's possible.</p> <p>20 QUESTIONS BY MR. KAWAMOTO:</p> <p>21 Q. Well, it's more than possible;</p> <p>22 it's likely, sir, isn't it?</p> <p>23 MR. TSAI: Object to the form.</p> <p>24 THE WITNESS: If you say so.</p> <p>25</p>

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<p>1 QUESTIONS BY MR. KAWAMOTO:</p> <p>2 Q. So going back to this document,</p> <p>3 I think it's Exhibit 6 --</p> <p>4 A. Exhibit 6?</p> <p>5 Q. Yes.</p> <p>6 We were looking at page --</p> <p>7 A. Okay.</p> <p>8 Q. -- 3 of 5.</p> <p>9 A. Uh-huh.</p> <p>10 Q. In terms of -- there's a</p> <p>11 paragraph here that says, "If the dosage</p> <p>12 customer service representatives are</p> <p>13 contacted by a new customer asking that a</p> <p>14 account be set up and the interview process</p> <p>15 yields questionable results, the CSR will</p> <p>16 obtain the following information from the</p> <p>17 customer and forward that information in an</p> <p>18 e-mail to the director of security as well as</p> <p>19 the customer service manager."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. And was that part of the</p> <p>23 enhanced SOM program?</p> <p>24 A. I believe so.</p> <p>25 Q. And do you recall this ever</p>	<p>1 customer service representatives about</p> <p>2 questionable customers?</p> <p>3 A. I don't remember.</p> <p>4 Q. And so during the five years</p> <p>5 that you were the customer service manager</p> <p>6 for dosage products, you don't recall ever</p> <p>7 receiving a customer service report</p> <p>8 recommending that an account not be set up;</p> <p>9 is that fair?</p> <p>10 A. I don't remember, yes.</p> <p>11 I don't know if that was part</p> <p>12 of the final -- how a draft the final -- this</p> <p>13 is the draft. I don't know if that was the</p> <p>14 final product or not.</p> <p>15 Q. Okay. So going down to the</p> <p>16 next section, which is "Customer Service</p> <p>17 Manager."</p> <p>18 A. Uh-huh.</p> <p>19 Q. It says -- well, actually, can</p> <p>20 you review that section?</p> <p>21 A. Okay.</p> <p>22 Q. So it references a peculiar</p> <p>23 order daily report.</p> <p>24 Was this part of the enhanced</p> <p>25 SOM program?</p>
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<p>1 occurring?</p> <p>2 A. Again, if -- this was a working</p> <p>3 document, and if -- this probably would have</p> <p>4 went to the director of security, and if he</p> <p>5 felt that we should not set them up, we</p> <p>6 probably would not.</p> <p>7 Q. Okay. But do you recall any</p> <p>8 instances where the director of security</p> <p>9 declined to set up an account because of</p> <p>10 concerns about the interview process?</p> <p>11 A. No. I don't recall that.</p> <p>12 Q. And this -- this -- this</p> <p>13 paragraph references both the director of the</p> <p>14 security as well as the customer service</p> <p>15 manager.</p> <p>16 A. Right.</p> <p>17 Q. Do you see that?</p> <p>18 A. Uh-huh.</p> <p>19 Q. And that would have been you</p> <p>20 for dosage products in the 2008 to 2013 time</p> <p>21 period?</p> <p>22 A. Going forward, it would have</p> <p>23 been me.</p> <p>24 Q. Okay. Do you recall ever</p> <p>25 receiving reports from the customers -- from</p>	<p>1 A. It was proposed. I don't think</p> <p>2 it ever went into effect.</p> <p>3 Q. Okay. So did you -- did you</p> <p>4 ultimately receive a report of suspicious</p> <p>5 orders?</p> <p>6 A. Yes. In August when we</p> <p>7 finalized --</p> <p>8 Q. Finalized the program?</p> <p>9 A. -- the program, yes.</p> <p>10 Q. In what way was that report</p> <p>11 different than the peculiar order daily</p> <p>12 report that's described here?</p> <p>13 A. There was more information that</p> <p>14 was used for determining whether an order was</p> <p>15 peculiar than what is outlined here.</p> <p>16 Q. Okay. And what was the</p> <p>17 additional information that was used?</p> <p>18 A. Yeah, like I mentioned before,</p> <p>19 it's got unusual large, unusual frequency and</p> <p>20 our deviation quantity to establish order</p> <p>21 pattern.</p> <p>22 From what I remember, it also</p> <p>23 looked at that -- that family that I talked</p> <p>24 about where if they ordered 50 pills, as you</p> <p>25 described it, and now they ordered 100 pills,</p>

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<p>1 it would look -- would be looking at the 2 total, not just that particular SKU. So that 3 was added into it.</p> <p>4 And I believe there's some 5 other factors that would -- that were put 6 into the -- into the program other than it 7 was just outlined here.</p> <p>8 Q. Okay. And going back to the 9 family point that you had.</p> <p>10 A. Uh-huh.</p> <p>11 Q. Is this a difference between 12 looking at orders on a SKU basis versus an 13 API basis? Is that one way to think of this?</p> <p>14 A. Yeah. Yes.</p> <p>15 Q. And so what is an API?</p> <p>16 A. Well, API is an active 17 pharmaceutical ingredient.</p> <p>18 Q. And what is --</p> <p>19 A. Essentially what that is is 20 that API is the active ingredient in a -- in 21 a -- let's use a tablet, for instance. To 22 make a tablet, you can't just make it from 23 the active ingredient. There's other 24 chemicals that have to be added to it so it 25 can be pressed into a tablet. Okay. That</p>	<p>1 that.</p> <p>2 What is the concern you have 3 with respect to looking at a SKU that is 4 fixed if you look at the API?</p> <p>5 That's what I'm trying to 6 understand.</p> <p>7 A. Okay. So if you had 5 -- 8 5 milligrams in a tablet and -- one tablet 9 and you had 10 milligrams in another tablet, 10 you would want to look at the total for that 11 particular -- the API of that particular 12 product. Okay.</p> <p>13 So if a customer ordered 14 10 milligrams of that family, say 15 hydrocodone, and then decided, "Well, I 16 ordered too many of those, I'm going to order 17 5 milligrams of that active ingredient" -- to 18 keep from the orders looking like they were 19 heavy, they could order one and one, one and 20 one, and it wouldn't trigger the two times or 21 whatever of the suspicious order program. 22 It's a way around the infrequent -- not 23 infrequent, but, you know, twice the amount 24 of a particular order.</p> <p>25 Follow me?</p>
<p style="text-align: center;">Page 179</p> <p>1 had no chemical or no -- how do I want to say 2 it? It did nothing for the patient, okay, 3 that had nothing to do with it. It was just 4 how to format a pill or that. So that would 5 be the inactive ingredients in a tablet.</p> <p>6 Does that make sense?</p> <p>7 Q. I believe I understand.</p> <p>8 I guess -- well, let me ask you 9 this.</p> <p>10 A. So let me better explain it.</p> <p>11 Q. Okay.</p> <p>12 A. Okay. We made -- say we wanted 13 to make hydrocodone, okay. That was the 14 active ingredient in the tablet.</p> <p>15 To that, we would add compac, 16 which is acetaminophen that was compressible. 17 Okay. So those two would be added together, 18 and they would be put in pill presses and 19 make the product, the end product.</p> <p>20 But the inactive ingredient had 21 no benefit to the -- or could -- did not have 22 any drug ingredient in it.</p> <p>23 Q. And so what is the -- what is 24 the diversion benefit of looking at the API 25 as opposed to the SKU? Or let me rephrase</p>	<p style="text-align: center;">Page 181</p> <p>1 Did I explain that well enough 2 for you?</p> <p>3 Q. Well, I'm still trying to 4 understand this. I guess let me -- let me 5 ask it this way then.</p> <p>6 A. All right.</p> <p>7 Q. What is -- what is the problem 8 by just looking at the prior order history on 9 a SKU basis? What -- if you were to do that, 10 what are you missing?</p> <p>11 A. On a SKU basis?</p> <p>12 Q. Yes.</p> <p>13 A. Okay.</p> <p>14 Q. How could you game the system 15 if it was based on a SKU basis as opposed to 16 the API basis?</p> <p>17 A. Okay. If I ordered, let's say, 18 on a SKU basis, a hundred tablets of this one 19 SKU, okay, then another SKU of the same 20 product, okay, had a different number of 21 tablets. Okay. If I ordered a hundred and 22 then I went over to the other one and I 23 ordered a hundred of that, okay, it would get 24 under that -- that frequency of, say, if I 25 ordered twice as many as normal of the</p>

<p style="text-align: right;">Page 182</p> <p>1 hundred.</p> <p>2 Q. Okay.</p> <p>3 A. Or twice as many of the 50. So</p> <p>4 if I split it up and ordered one and one,</p> <p>5 okay, it wouldn't hit that threshold, okay.</p> <p>6 They're ordering twice as many of the</p> <p>7 hundreds as they normally do, if they bounce</p> <p>8 back and forth.</p> <p>9 Does that make sense?</p> <p>10 Q. Okay. I think I understand.</p> <p>11 And would it solve this problem</p> <p>12 if you were to look at it on a SKU-by-SKU</p> <p>13 basis or --</p> <p>14 A. I don't understand your</p> <p>15 question, to solve this problem.</p> <p>16 Q. Actually, I'll withdraw that</p> <p>17 question. I think I understand what you're</p> <p>18 getting at.</p> <p>19 Okay. And so other than</p> <p>20 looking at essentially -- well, strike that.</p> <p>21 So with respect to the peculiar</p> <p>22 order report that you were receiving, in</p> <p>23 addition to the information regarding size,</p> <p>24 frequency and order pattern, it also took</p> <p>25 into account the family of drugs, I guess, or</p>	<p style="text-align: right;">Page 184</p> <p>1 list was entirely dependent on the DEA</p> <p>2 saying, "Don't ship to this person"; is that</p> <p>3 fair?</p> <p>4 A. Yes.</p> <p>5 Well, no. That we determine as</p> <p>6 part of the program of suspicious activity.</p> <p>7 So if we had found a customer</p> <p>8 that was a suspicious order, we had said was</p> <p>9 a suspicious order, and we could not verify</p> <p>10 that it was a good order, then there was</p> <p>11 flags in the system created that would flag</p> <p>12 that customer that we could not accept one of</p> <p>13 their -- their orders. That was part -- that</p> <p>14 was part of the new program.</p> <p>15 Q. And so --</p> <p>16 A. Along with what the DEA sent</p> <p>17 out.</p> <p>18 Q. So just so I understand, there</p> <p>19 are two ways to get on this list: One of</p> <p>20 them would be the DEA would put them on the</p> <p>21 list.</p> <p>22 A. Right.</p> <p>23 Q. The other way would be</p> <p>24 Mallinckrodt would independently determine</p> <p>25 based on the orders they're submitting that</p>
<p style="text-align: right;">Page 183</p> <p>1 they looked at things on an API basis.</p> <p>2 A. Right.</p> <p>3 Q. Were there other factors as</p> <p>4 well?</p> <p>5 A. There were, but I don't</p> <p>6 remember all of them.</p> <p>7 Q. Now, do you see the reference</p> <p>8 to a do-not-ship list?</p> <p>9 A. Yes.</p> <p>10 Q. Was that part of the enhanced</p> <p>11 SOM program?</p> <p>12 A. Yes. What would -- well, it</p> <p>13 was an ongoing -- I mean, Karen Harper would</p> <p>14 get a report from the DEA of -- of customers</p> <p>15 or other than customers that were potential</p> <p>16 customers from the DEA that we were not to be</p> <p>17 shipping to any -- it's kind of a warning</p> <p>18 list, do not ship to these customers or</p> <p>19 whatever.</p> <p>20 And then what we would do is</p> <p>21 flag -- if it was an existing customer, we</p> <p>22 would flag that customer so that we could not</p> <p>23 accept any orders into the system for that</p> <p>24 customer.</p> <p>25 Q. So this -- this do-not-ship</p>	<p style="text-align: right;">Page 185</p> <p>1 they -- that they are -- you know, their</p> <p>2 orders are problematic or that there are</p> <p>3 diversion concerns --</p> <p>4 A. Yes.</p> <p>5 Q. -- and put them on this list.</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Who maintained this</p> <p>8 list?</p> <p>9 A. It was maintained in our order</p> <p>10 entry system, and customer service -- or -- I</p> <p>11 believe that customer service was in charge</p> <p>12 of that, if it ever occurred.</p> <p>13 Q. Okay. Do you recall how many</p> <p>14 entities were put on this list in the 2008</p> <p>15 through 2013 time period?</p> <p>16 A. We did not have any suspicious</p> <p>17 orders at that time, during that time period.</p> <p>18 Q. So is it fair to say then that</p> <p>19 no one was on this do-not-ship list?</p> <p>20 A. Through the monitoring program.</p> <p>21 Q. Okay. So the only entities</p> <p>22 that were put on this list then were from</p> <p>23 DEA?</p> <p>24 A. At that time, yes.</p> <p>25 Q. Then do you see at the very</p>

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<p>1 bottom of the page --</p> <p>2 A. Proposed preliminary dosage.</p> <p>3 Q. Yeah, proposed preliminary</p> <p>4 dosage formula, and then it follows on the</p> <p>5 following page as to what that formula is.</p> <p>6 A. And that's what I was trying to</p> <p>7 explain to you where it says add purchase</p> <p>8 quantities by product, all oxy products and</p> <p>9 again by individual SKUs. Okay. So it's</p> <p>10 looking at the -- the API also.</p> <p>11 Okay.</p> <p>12 Q. And so --</p> <p>13 A. It's pretty detailed.</p> <p>14 Q. So does this -- is this formula</p> <p>15 an accurate depiction of the formula that was</p> <p>16 applied to dosage products for the 2008</p> <p>17 through 2013 time period?</p> <p>18 A. Not 2008. I think this was</p> <p>19 in --</p> <p>20 Q. Sorry, my apologies.</p> <p>21 A. 2000 --</p> <p>22 Q. From fall of 2009 until 2013,</p> <p>23 is this the formula that was applied to</p> <p>24 dosage products?</p> <p>25 A. I believe that's -- again, this</p>	<p>1 taking the current order and comparing it to</p> <p>2 the rolling 12-month --</p> <p>3 A. Right.</p> <p>4 Q. I'll strike that.</p> <p>5 It was taking the current -- it</p> <p>6 was taking the current order and comparing it</p> <p>7 to the rolling 12-month average times [REDACTED]; is</p> <p>8 that accurate?</p> <p>9 A. Correct. Uh-huh.</p> <p>10 Q. And so this new formula was</p> <p>11 comparing the current order to a rolling</p> <p>12 12-month average times [REDACTED], isn't that the</p> <p>13 factor for -- if there's a factor that</p> <p>14 says -- it says factor Schedule II controlled</p> <p>15 substances?</p> <p>16 A. Well, that -- that along with</p> <p>17 some other things that are also here.</p> <p>18 Customers will multiply -- with multiple</p> <p>19 ship-to locations should have their total</p> <p>20 aggregated at the sold-to level but also</p> <p>21 reviewed at the ship-to level. Okay.</p> <p>22 So it was not only looking at</p> <p>23 the individual -- it was looking at just not</p> <p>24 the individual distributors, but it was</p> <p>25 looking at the total that that distributor</p>
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<p>1 was a work-in-progress draft, but I believe</p> <p>2 that this was part of that end product.</p> <p>3 Q. So looking at the end</p> <p>4 program --</p> <p>5 A. Uh-huh.</p> <p>6 Q. -- what was the formula applied</p> <p>7 to dosage products from fall of 2009</p> <p>8 through 2013? Can you tell me --</p> <p>9 A. What was the formula?</p> <p>10 Q. Yes, what was the formula.</p> <p>11 A. Well, it's written out here</p> <p>12 exactly what the formula consisted of.</p> <p>13 Q. So for --</p> <p>14 A. It's pretty complicated, so for</p> <p>15 me to verbally tell you, I don't know if I --</p> <p>16 if I could describe it well enough.</p> <p>17 Q. Well --</p> <p>18 A. It looked --</p> <p>19 Q. Sorry.</p> <p>20 A. It looked at order quantity --</p> <p>21 there was just a number of them that I don't</p> <p>22 remember all the formula. I couldn't spell</p> <p>23 it out -- spell it out for you anymore.</p> <p>24 Q. Well, if we look at the</p> <p>25 pre-2007 formula, it was looking at -- it was</p>	<p>1 was purchasing.</p> <p>2 Had customer months for every</p> <p>3 record used in the above total month within</p> <p>4 the last -- customer center. Went down to</p> <p>5 zero.</p> <p>6 So okay. It's just writing --</p> <p>7 this is just writing out the formula of how</p> <p>8 it should be done.</p> <p>9 So you take that information,</p> <p>10 you divide the total quantity purchased by</p> <p>11 total customer months, then multiply -- okay,</p> <p>12 I'm sorry, what was your -- what were you</p> <p>13 going to say?</p> <p>14 Q. Well, looking -- I'm trying to</p> <p>15 understand the difference between the</p> <p>16 pre-2007 formula, which was for dosage</p> <p>17 products a rolling 12-month average times</p> <p>18 [REDACTED] --</p> <p>19 A. Okay.</p> <p>20 Q. -- and the formula under the</p> <p>21 enhanced SOM program.</p> <p>22 A. Okay. This is one part of the</p> <p>23 formula -- this is a formula right here of</p> <p>24 what it should look like. It also looked at</p> <p>25 your regular order patterns, okay. It looked</p>

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<p>1 at, like I said, at the family, or the API, 2 which we didn't look at pre-2009. The 3 pre-2009 just looked at the order by double, 4 okay.</p> <p>5 So I think I've said three 6 things already that the other -- that the 7 original report that we sent to the DEA on a 8 monthly basis did not have.</p> <p>9 And I don't think this is the 10 final version. It had even more.</p> <p>11 Q. And in terms of how this 12 formula was -- well, strike that.</p> <p>13 How was this formula applied to 14 Mallinckrodt orders?</p> <p>15 A. Okay. So this was -- this was 16 put in in our order entry system, and on a -- 17 on a daily basis all orders were compared to 18 the log rhythms {sic} that we had set in 19 place for our customers and orders.</p> <p>20 If there was anything that did 21 not fit the normal order pattern or what we 22 would consider the normal order pattern based 23 upon our guidelines and what we had put in 24 place, it would flag that order and a report 25 would print out that I looked at on a daily</p>	<p>1 Another example is if it was, 2 say, they hadn't ordered for two or three 3 months and then all of a sudden we received a 4 large order from a customer, that would be 5 considered an irregular order pattern. Okay. 6 That would kick out on this report.</p> <p>7 Again, I -- I talk about the 8 API. If their total API for an order was 9 greater than whatever the criteria was for 10 that, it would kick out.</p> <p>11 Those were reasons for the 12 order to kick out on the report.</p> <p>13 Q. And where -- was this formula 14 written down somewhere?</p> <p>15 A. I believe what we put into the 16 computer was probably written down somewhere. 17 I don't remember exactly.</p> <p>18 This was given to our 19 information services people that were on the 20 team and it was put into their systems, so it 21 was probably -- it was documented by them.</p> <p>22 Q. Okay. And did you work with 23 anyone in particular in the information 24 services team?</p> <p>25 A. I believe it was on the --</p>
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<p>1 basis.</p> <p>2 And it would show me the orders 3 that had been flagged as peculiar. And as 4 discussed earlier, I would take -- is that 5 what you're looking for?</p> <p>6 Q. Yes.</p> <p>7 A. Okay.</p> <p>8 Q. And how would it -- how 9 would -- how would the program tell whether 10 an order did not fit the normal order 11 pattern?</p> <p>12 A. Based upon these formulas that 13 were put into the system.</p> <p>14 Q. But what -- I mean, what 15 specifically was this formula supposed to 16 take into account? What specifically was the 17 formula looking for in determining what a 18 normal order pattern was and what a deviation 19 from that was?</p> <p>20 A. If it was -- if it didn't meet 21 the criteria of the formulas that -- that we 22 had put in place as far as -- for example, 23 twice the orders in a rolling 12-month 24 period, it would kick out. That's just one 25 example. Okay.</p>	<p>1 let's see.</p> <p>2 I don't see any of the people 3 listed from IS on this team that -- this 4 report here, but there were -- I don't -- I 5 don't remember the people's names that were 6 from -- I remember Steve, but I don't 7 remember his last name.</p> <p>8 So they were -- they were part 9 of the team and they were brought in when we 10 came -- came to a point where we were ready 11 to give them some -- give them information 12 that we wanted implemented into the computer 13 system, and we would have to write up a 14 document spelling out exactly what it was 15 that we wanted to be put into the system.</p> <p>16 Q. And did you write up this 17 document, or did someone else write it?</p> <p>18 A. Someone else wrote it up. I 19 don't remember who exactly.</p> <p>20 Q. Do you -- and you don't recall 21 who?</p> <p>22 A. No.</p> <p>23 Q. Okay. And what -- you 24 referenced an IS computer system.</p> <p>25 Did that system have a name?</p>

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<p>1 A. That -- that would be our order 2 entry system.</p> <p>3 Q. So the order entry system, was 4 that the JD Edwards system?</p> <p>5 A. Yes.</p> <p>6 Q. And so as part of the computer 7 code in this JD Edwards system, you would 8 have this formula that got applied to all of 9 the orders?</p> <p>10 A. That's correct.</p> <p>11 Q. Okay. And so if an order 12 wasn't flagged by application of this 13 algorithm, that order didn't get examined or 14 looked at; is that correct?</p> <p>15 A. That's correct.</p> <p>16 Q. Okay. So if your -- if your 17 algorithm was faulty or had a gap or was 18 missing something, then, you know, 19 potentially orders that were problematic 20 could get through; is that fair?</p> <p>21 MR. TSAI: Objection.</p> <p>22 THE WITNESS: That's a 23 possibility.</p> <p>24 QUESTIONS BY MR. KAWAMOTO:</p> <p>25 Q. In other words, your suspicious</p>	<p>1 implementation, testing and so forth.</p> <p>2 Q. And do you recall a memo ever 3 being drafted that would lay out this 4 algorithm and how it worked, or was it just 5 computer code that was put into the computer 6 program?</p> <p>7 A. There was probably a document. 8 I don't know -- I don't remember where the 9 document -- if -- who had it, but the 10 document had to be developed to give to IT. 11 They had a -- they had a form that had to be 12 filled out and submitted to them for 13 evaluation and coding and amount of resources 14 needed and time needed to do the 15 implementation.</p> <p>16 Q. And do you recall -- did this 17 form have a name?</p> <p>18 A. I don't recall. (Mallinckrodt-Rausch Exhibit 7 marked for identification.)</p> <p>19 QUESTIONS BY MR. KAWAMOTO:</p> <p>20 Q. Okay. So I would like to mark 21 as Exhibit 7 another document. It bears a 22 Bates number MNK-T1_477900. 23 So if you could take a minute</p>
<p style="text-align: center;">Page 195</p> <p>1 order -- your enhanced suspicious order 2 monitoring program was, you know, only as 3 good or as bad as this algorithm was; is that 4 fair?</p> <p>5 A. That would be --</p> <p>6 MR. TSAI: Object as to form.</p> <p>7 QUESTIONS BY MR. KAWAMOTO:</p> <p>8 Q. And who was -- other than you, 9 who helped develop this algorithm?</p> <p>10 A. Everybody on the team was -- 11 had input on what they felt, and that was 12 part of the -- the team that was put together 13 to work on what we felt should be in the -- 14 in the order entry -- what we should put in 15 the order entry system or this suspicious 16 order program.</p> <p>17 So Cathy Stewart, Sue Marlatt 18 was probably involved in it, myself, Karen 19 Harper, and, like I said, IT would probably 20 have -- would have had somebody in there at 21 the point where we would need them as far as 22 advising us what was possible.</p> <p>23 And then we would write up the 24 document that we wanted to have put into the 25 system and submit that to IT for</p>	<p style="text-align: center;">Page 197</p> <p>1 to review this document and let me know when 2 you're done.</p> <p>3 And I have -- I mean, it's a 4 relatively lengthy document, so I have, you 5 know, specific questions relating to certain 6 portions of it.</p> <p>7 A. Do you want me to read all of 8 it?</p> <p>9 Q. No. 10 Have you read the first half?</p> <p>11 A. Yes, I've --</p> <p>12 Q. Okay.</p> <p>13 A. -- scanned through it, yes.</p> <p>14 Q. So have you ever seen this 15 document before?</p> <p>16 A. I don't remember it.</p> <p>17 Q. Okay. Now, is my understanding 18 correct that this document is, to some 19 extent, a chronology or a timeline of the 20 development of the enhanced suspicious order 21 monitoring program?</p> <p>22 A. It looks like it, yes.</p> <p>23 Q. Okay. And at the very top it 24 says, "Activities 08/2008 through 08/2010." 25 Do you see that?</p>

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	<p>1 A. Yes.</p> <p>2 Q. Okay. And the suspicious --</p> <p>3 the enhanced suspicious order monitoring</p> <p>4 program with its revised algorithm launched</p> <p>5 in the fall of 2009; is that correct?</p> <p>6 A. Correct.</p> <p>7 Q. Okay.</p> <p>8 A. Oh, Robyn McHale was the person</p> <p>9 that -- from IT that worked on it. She was a</p> <p>10 freelance IT person.</p> <p>11 You know what that is, right?</p> <p>12 Q. Actually, I don't. I'm sorry.</p> <p>13 A. Okay. It's a person that</p> <p>14 worked independently for themselves and then</p> <p>15 we would hire them to do work for us.</p> <p>16 Q. Essentially like a consultant;</p> <p>17 is that fair?</p> <p>18 A. Yeah, that would be a name for</p> <p>19 it.</p> <p>20 Q. And did she have a -- did she</p> <p>21 have a Mallinckrodt e-mail, a Mallinckrodt</p> <p>22 account?</p> <p>23 A. At that time she probably did,</p> <p>24 but I don't know if she still works with</p> <p>25 Mallinckrodt or not.</p>	<p>1 A. The IS department, I would say,</p> <p>2 would have that.</p> <p>3 Q. Okay. Okay. So directing your</p> <p>4 attention to page 2 of this timeline.</p> <p>5 A. Okay.</p> <p>6 Q. Do you see there's an entry</p> <p>7 involving you, it's 03/02/2009?</p> <p>8 A. Okay.</p> <p>9 Q. And it says, "Jim Rausch</p> <p>10 continues work with IS to define the criteria</p> <p>11 of what would be a peculiar order and how to</p> <p>12 determine programmatic flags for detection."</p> <p>13 Is that accurate?</p> <p>14 A. Yes.</p> <p>15 Let me explain this. I was --</p> <p>16 at the time I was fairly new to dosage, and</p> <p>17 Cathy was fairly new to bulk, so she was</p> <p>18 working with the dosage log rhythms {sic} and</p> <p>19 I was working on the bulk, because she had</p> <p>20 more experience on the dosage side.</p> <p>21 Q. And then it says, "CSR</p> <p>22 managers," that would have been you and</p> <p>23 Cathy?</p> <p>24 A. Where are we at?</p> <p>25 Q. The entry below that?</p>
	Page 199	Page 201
	<p>1 Q. Do you know if she had an</p> <p>2 office at Mallinckrodt?</p> <p>3 A. She had a cubicle, yes. I</p> <p>4 believe she did. Either -- at times she</p> <p>5 worked from her home, too, but -- I think she</p> <p>6 did, but I don't remember anymore.</p> <p>7 Q. Okay. And she would have been</p> <p>8 the person --</p> <p>9 A. She was one of the people that</p> <p>10 I remember from IS that was working on</p> <p>11 implementing this into the JD Edwards system.</p> <p>12 Q. And so she would likely have</p> <p>13 the document that set out what the exact</p> <p>14 algorithm was?</p> <p>15 A. She could be, but I would say</p> <p>16 that would -- probably since she was a</p> <p>17 consultant, she would not be the person that</p> <p>18 would -- that would have it now. It would</p> <p>19 probably reside with somebody in IT that</p> <p>20 actually worked for Mallinckrodt.</p> <p>21 Q. Okay. And that person would</p> <p>22 likely have the -- not only the enhanced</p> <p>23 suspicious order monitoring algorithm as of</p> <p>24 2009, but all the variations of it up until</p> <p>25 present; is that correct?</p>	<p>1 A. Oh.</p> <p>2 Q. "The CSR managers begin review</p> <p>3 of customer segmentation categories within</p> <p>4 the order entry system to determine if</p> <p>5 separate algorithms to define peculiar order</p> <p>6 patterns will be necessary based on a class</p> <p>7 of trade."</p> <p>8 A. Correct.</p> <p>9 Q. Do you know what the final</p> <p>10 determination of that was?</p> <p>11 A. That we probably would have</p> <p>12 separate needs depending on our customers.</p> <p>13 Q. So this means that you would</p> <p>14 have separate algorithms depending on the</p> <p>15 class of customer?</p> <p>16 A. What it means is based upon our</p> <p>17 business needs, okay. What we did for dosage</p> <p>18 may be different from what we do for bulk as</p> <p>19 far as what we implemented.</p> <p>20 Q. Okay. But within the dosage</p> <p>21 algorithm --</p> <p>22 A. Yeah.</p> <p>23 Q. -- it was not further</p> <p>24 subdivided into different classes of</p> <p>25 customers?</p>

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1	A. No.	1 through the top e-mail, can we take a
2	Q. So you had one -- you had	2 break?
3	one -- for dosage products, you had one	3 MR. KAWAMOTO: Sure.
4	algorithm that was applied to wholesalers,	4 THE WITNESS: Okay. So this
5	distributors, retail pharmacies?	5 was an e-mail -- or this was what I
6	A. Correct.	6 believe -- oh, okay. It is from
7	Q. The same algorithm?	7 Cathy.
8	A. If I remember. Again, I didn't	8 Cathy, like I said, was working
9	develop, but I believe so.	9 on the formulas for the dosage
10	Q. Okay. And then do you see	10 business, and I think this was --
11	6/29/2009, it says, "Revised customer	11 somebody says -- this doesn't make
12	questionnaires are submitted to legal that	12 sense.
13	have been updated based upon CSR focus group	13 E-mails from Cathy. I'm
14	meetings Jim Rausch and Cathy Stewart	14 getting confused.
15	conducted with CSRs"?	15 I'm not sure if that's Karen
16	A. Yes, I see that. Okay.	16 that's saying that, but --
17	Q. What is that in reference to?	17 QUESTIONS BY MR. KAWAMOTO:
18	A. It was a questionnaire that I	18 Q. Well, the top line says, "work
19	think we worked on, but I'm not sure if we	19 continues with IS on algorithms, e-mail
20	ever did -- what it composed of. I don't	20 follows from Cathy Stewart."
21	remember it.	21 A. Right.
22	Q. And so are you not sure whether	22 Q. And it -- that seems to
23	it was ultimately ever sent out?	23 indicate that Cathy Stewart is saying --
24	A. Correct. I'm not sure what we	24 A. Okay. Cathy Stewart sent an
25	did with that.	25 e-mail to Robyn. "I'm sorry to ask this
	Page 203	Page 205
1	Q. And it says, "CSR focus group	1 again, but my notes -- aren't very clear.
2	meetings."	2 This is a correct ship to report classes on
3	What -- do you recall what the	3 this report is for total quantity."
4	focus group meetings were?	4 I think she was reviewing
5	A. No, I don't.	5 with -- what Robyn had presented to her and
6	Q. Okay. Now, it says 7/2009,	6 Cathy was just questioning if that's what she
7	"CDIG begin sending out SM customer	7 had asked for or not.
8	questionnaires."	8 Q. Okay. And then -- well, do you
9	What is "CDIG"?	9 see the paragraph in the middle of the page
10	A. Customer data integrity group.	10 that starts with, "This was -- this was we
11	Q. And you don't know whether they	11 can see that this customer"?
12	sent out revised questionnaires or the old	12 Do you see that?
13	questionnaires?	13 A. Uh-huh.
14	A. No, you would have to ask	14 Q. And then it's below the -- what
15	somebody in that group.	15 appears to be both months and, I guess,
16	Q. Okay. Now, do you see at the	16 hypothetical orders.
17	top of page 3 it says, "Work continues with	17 Do you see that?
18	IS on algorithms."	18 A. Yes.
19	A. Uh-huh.	19 Q. Okay. So what -- what is
20	Q. "E-mail follows from Cathy	20 Cathy's concern?
21	Stewart."	21 A. I'm not sure. You would have
22	A. Right.	22 to ask Cathy about that.
23	Q. And can you review that e-mail	23 Q. Okay.
24	for me?	24 A. From -- this was -- okay. I
25	MR. TSAI: Dean, after we go	25 think her -- what she was saying that

<p style="text-align: right;">Page 206</p> <p>1 their -- their gradual increase of orders 2 rather than jumping from 100 to 200 would 3 trigger the 2 X formula versus if they 4 gradually increase from 100 to 125 to 150 to 5 175 would not trigger that -- that to kick 6 out.</p> <p>7 Q. In other words, it would be 8 possible over time to actually have a 9 significant increase in the monthly order 10 that wouldn't be triggered by the algorithm; 11 is that fair?</p> <p>12 A. Right. And I think that's what 13 Cathy is pointing out --</p> <p>14 Q. Okay.</p> <p>15 A. -- is that they could get 16 around it that way. So we were trying to 17 work on a system that everything that we 18 possibly could think of of getting around 19 placing an order that we didn't feel it was 20 legitimate, we were trying to think of 21 everything possible.</p> <p>22 Q. And so how was this concern 23 addressed?</p> <p>24 A. I don't remember. I think it 25 was addressed, but I don't remember exactly</p>	<p style="text-align: right;">Page 208</p> <p>1 Q. But -- but you're not aware 2 of -- you're not aware of what fix, if any, 3 was applied to address this concern?</p> <p>4 A. No.</p> <p>5 MR. KAWAMOTO: Okay. So why 6 don't we take a break now.</p> <p>7 VIDEOGRAPHER: We're going off 8 the record at 2:35 p.m.</p> <p>9 (Off the record at 2:35 p.m.)</p> <p>10 VIDEOGRAPHER: We are back on 11 the record at 2:51 p.m.</p> <p>12 QUESTIONS BY MR. KAWAMOTO:</p> <p>13 Q. So if we could return to the 14 document that you were just looking at, I 15 believe it is Exhibit 7.</p> <p>16 A. Okay.</p> <p>17 Q. Okay?</p> <p>18 Now, you had -- we were 19 discussing the gradual increase in orders 20 over time, and you had indicated that's 21 something that Cathy Stewart would be 22 knowledgeable about in the dosage area.</p> <p>23 A. That's correct.</p> <p>24 Q. With respect to the bulk area, 25 which was your area of expertise, wouldn't</p>
<p style="text-align: right;">Page 207</p> <p>1 how.</p> <p>2 Q. Okay. And so it was possible 3 that it -- was it possible that it wasn't 4 addressed?</p> <p>5 A. I think you would have to talk 6 to Cathy about that.</p> <p>7 Q. Okay. Do you know --</p> <p>8 A. Like I said, she was working on 9 the dosage log rhythms {sic} and I was 10 working on the bulk because that's what we 11 were familiar with.</p> <p>12 Q. Do you know if anyone else 13 raised a similar concern, namely that you 14 could have gradual increases that over time 15 result in a significant increase that 16 wouldn't be caught?</p> <p>17 A. If anybody else --</p> <p>18 Q. Yeah, do you know if this 19 concern was raised by anyone else?</p> <p>20 A. I'm not sure. It could have 21 been. I mean, the team working on this was 22 looking at all possibilities. They're trying 23 to think of what they could do, somebody -- a 24 customer could do to try and get around the 25 system.</p>	<p style="text-align: right;">Page 209</p> <p>1 that same problem also apply?</p> <p>2 A. Yeah, the same problem could 3 apply, yes.</p> <p>4 Q. And so how was that addressed 5 in the bulk context?</p> <p>6 A. I don't remember, but I'm 7 sure -- is it in here? We would have put 8 something in based upon the bulk side also. 9 I don't remember exactly what it was.</p> <p>10 Q. Well, how -- how would one fix 11 this problem?</p> <p>12 A. How would one fix this problem?</p> <p>13 Q. Yes. I mean, hypothetically, 14 how would you fix a problem? I mean, if you 15 have a numeric formula that's based on 16 looking at a current order and then comparing 17 it to sort of prior order history, I mean, 18 how would you -- how would you modify the 19 formula to address that problem?</p> <p>20 A. It would probably be based upon 21 an average versus looking at -- and I'm just 22 guessing at this point because I don't 23 remember anymore. I'll just leave it at 24 that: I don't remember anymore how we 25 addressed it.</p>

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<p>1 Q. But mathematically speaking, 2 what -- I mean, what would you do? Because, 3 I mean, you're already basing that formula on 4 an average, aren't you?</p> <p>5 A. Correct. Average period of 6 time of ordering.</p> <p>7 Q. Yes.</p> <p>8 A. Yes.</p> <p>9 So if they went from 100 to 150 10 to 175 to 200 over a period of time, I guess 11 you would try to divide that and come up with 12 an average. And if it went two times over 13 that average, it might kick it out that way.</p> <p>14 Q. Well, I mean, isn't the only 15 way to decrease the [REDACTED] times -- so instead 16 of looking at two times, you would look at, 17 for example, [REDACTED]?</p> <p>18 A. That's one approach. I'm not 19 sure if that's the only approach.</p> <p>20 Q. Well, what -- what -- what is 21 the other approach that you're --</p> <p>22 A. I think -- that's what I was 23 just talking about. If you looked at the 24 average of, say, 125, 150, 175, 200, which is 25 a general increase, if you took that average</p>	<p>1 Do you see that?</p> <p>2 A. Uh-huh.</p> <p>3 Q. So how long was the peculiar 4 order report that you ultimately ended up 5 reviewing after the program went live in fall 6 of 2009?</p> <p>7 A. It varied from day to day. On 8 an average, I would say it's less than 9 probably -- probably 10 or 15.</p> <p>10 Q. And that's 10 or 15 pages?</p> <p>11 A. Yes.</p> <p>12 Q. And how many orders would be on 13 that report?</p> <p>14 A. Maybe five or so orders on a 15 page.</p> <p>16 Q. So anywhere from 25 to 50 17 orders; is that fair?</p> <p>18 A. It could be on a day, daily 19 basis.</p> <p>20 Q. And who was responsible for 21 investigating and determining whether there 22 was a valid business -- well, strike that.</p> <p>23 What did you do with those 25 24 or 50 orders that would show up on your 25 report on a daily basis?</p>
Page 211	Page 213
<p>1 and say it was 150, if the orders were two 2 times that 150, then it would kick it out. 3 That's one way of doing it.</p> <p>4 Or you could do it like you 5 said and make it [REDACTED] or [REDACTED] or [REDACTED] or -- 6 there's probably a number of ways of doing it 7 besides that, but I don't remember what we 8 landed on.</p> <p>9 Q. And in terms of the average, 10 though, you would -- so you would -- you 11 would try to shorten the average period -- 12 I'm just trying to understand how modifying 13 the average --</p> <p>14 A. I understand what you're -- 15 what you're asking, but I don't remember what 16 we did.</p> <p>17 Q. Okay. And to be clear, you're 18 not even sure that this problem was 19 addressed, are you?</p> <p>20 A. I don't remember.</p> <p>21 Q. So turning to page 4, at the 22 very top it says, "Work continues with IS 23 peculiar order report being generated based 24 upon algorithm settings that's 49 pages 25 long."</p>	<p>1 A. I would review them to see if 2 there's anything that I saw that would kick 3 that order out, because it would give us 4 different histories of that particular 5 customer and what they ordered and that type 6 of thing. And if I could see something that 7 would validate the order that was flagged, I 8 would let the order go.</p> <p>9 If I couldn't validate it, then 10 I would go to the CSRs like I explained 11 earlier, the process, CSR, business manager, 12 sales rep, and try to get this explained.</p> <p>13 Q. And were you doing all 25 to 50 14 orders, or was someone else also doing orders 15 for you?</p> <p>16 A. I was doing it.</p> <p>17 Q. So you were the only one 18 essentially doing it?</p> <p>19 A. Reviewing that.</p> <p>20 And it could -- it could have 21 been less. I don't remember particularly. 22 It could have been five. I don't know, five 23 to ten, if that many.</p> <p>24 Q. And roughly how long did it 25 take you? What's your -- well, strike that.</p>

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<p>1 What's your recollection as to 2 how long it took you? 3 A. A couple hours a day. 4 And that didn't entail -- if 5 I couldn't -- if I couldn't come up with a 6 solution of bringing it to the business 7 manager or to the sales rep, we tried to get 8 it resolved as soon as possible, hopefully by 9 the -- the end of the day, if possible. If 10 not, it may take a day or two to be resolved, 11 depending on where the sales person was or 12 where the business manager -- if I couldn't 13 get ahold of them right away. But those were 14 not that many orders. 15 Q. And so what's the maximum that 16 you could review, the maximum number of 17 orders that you could review at any day? 18 A. The maximum that I could 19 review? 20 Q. Well, I mean, would it be 21 possible for you to review 200 orders? 22 MR. TSAI: Object to the form. 23 THE WITNESS: No, but to answer 24 your -- to answer that, I would say 25 there was not the case where I was</p>	<p>1 primary in the morning and the afternoon -- 2 A. Right. That's when the reports 3 came out. 4 Q. Okay. And so did they come out 5 twice daily? 6 A. I believe they did, yes. 7 Q. And if this was primary for the 8 morning and this was primary for the 9 afternoon -- 10 A. It took up a good bit of my 11 time. 12 Q. Yes. 13 When did you have time to get 14 your other work done? 15 MR. TSAI: Object to the form. 16 THE WITNESS: Could you be more 17 specific? 18 QUESTIONS BY MR. KAWAMOTO: 19 Q. Sure. 20 If this was your primary task 21 in the morning and your primary task in the 22 afternoon -- I mean, the working day is 23 generally just divided into morning and 24 afternoon -- 25 A. Right.</p>
<p>1 being asked to -- or seeing 200 orders 2 on a daily basis. 3 QUESTIONS BY MR. KAWAMOTO: 4 Q. Was there anyone else at the 5 company other than you that could review 6 these orders? 7 A. Yes. As I mentioned before, 8 the customer service rep that sat in for me 9 when I was not there. 10 Q. But as a general matter, it was 11 just you reviewing these orders? 12 A. Correct. 13 Q. And did you have other job 14 responsibilities in addition to reviewing 15 these orders? 16 A. Yes. 17 Q. What were they? 18 A. I oversaw the customer service 19 group. I had a pretty -- pretty senior 20 group, so just solving problems or questions 21 that they may have, meeting with other people 22 on other business on a daily basis. But this 23 was -- this was primary in the morning and 24 the afternoon. 25 Q. Well, it was -- if it was</p>	<p>1 Q. -- so -- 2 A. Yeah, we're talking an hour or 3 so in the morning and an hour or so in the 4 afternoon of reviewing these orders. 5 Q. And so do you see the entry, 6 that 10/27/09, "peculiar order report being 7 generated based on algorithm is 150 dosage 8 orders per day and 170 bulk API orders per 9 day"?" 10 A. I see that. 11 Q. Okay. Would it have been 12 possible for you to review 150 dosage orders 13 per day? 14 A. No, it would not. 15 Now, keep in mind this was 16 based upon the working document, or what we 17 were looking at as far as suspicious order 18 monitoring program based upon different 19 criteria. 20 Now, as we went along, there 21 was some things that were not working that 22 created this problem of having so many. That 23 had nothing to do with what we wanted to look 24 at, but it was put into the system. 25 And I think you can say there</p>

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<p>1 was some statistical problems that needed to 2 be fine-tuned. So it was kicking out orders 3 that shouldn't have been kicked out. 4 And this was an IS -- this was 5 an IS issue. 6 Q. And what is your basis for 7 saying that it was kicking out orders that 8 shouldn't have been kicked out? 9 Well, let me rephrase that. 10 What are examples of orders that were being 11 kicked out that shouldn't have been? 12 A. Well, right here, I don't 13 remember exactly what this was about, where 14 it says, "The 30-day cumulative algorithm is 15 turned off because that specific trigger was 16 not spelled out in HDMA guidance and has 17 inflated the peculiar order count." 18 So that's one instance where it 19 was inflating the number of orders that we 20 were looking at. 21 Q. And what is the 30-day 22 cumulative algorithm? Do you know what that 23 is? 24 A. I don't remember. 25 Q. Now, from this entry, it</p>	<p>1 A. Uh-huh. 2 Q. -- when you have it -- when you 3 have it turned on, it is kicking out, you 4 know, some amount of orders. Or I guess to 5 put it more accurately, it's flagging a 6 certain amount of orders as peculiar; is that 7 correct? 8 A. Correct. 9 Q. And then when you remove this, 10 when you turn it off, those orders are no 11 longer flagged as peculiar; is that right? 12 A. Correct. 13 Q. Was any analysis ever done to, 14 you know, verify or confirm that those orders 15 were in fact not peculiar? 16 A. I don't remember. 17 Q. If that analysis were done, who 18 would have it? 19 A. I'm not sure who would have it 20 at this time. 21 Q. Now, as a practical matter, you 22 can't review 150 orders per day, correct? 23 A. That would be difficult. 24 Q. And so if you had a program 25 that were -- that was identifying 150 orders,</p>
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<p>1 indicates that the 30-day cumulative 2 algorithm was not spelled out in HDMA 3 guidance. But that's not the same thing as 4 saying that this algorithm wasn't going to 5 provide valuable information on peculiar 6 orders, is it? 7 MR. TSAI: Object to the form. 8 THE WITNESS: No, I don't think 9 it's saying that. I'm not sure what 10 it's saying there. 11 QUESTIONS BY MR. KAWAMOTO: 12 Q. Okay. Was there any analysis 13 done on the impact of removing the 30-day 14 cumulative algorithm with respect to the 15 orders that were no longer being kicked out? 16 A. Well, as I had mentioned 17 earlier, you know, what we did was we -- we 18 test ran this and massaged it as it went 19 along to see if it was doing the job we 20 wanted it to do as far as looking at the 21 orders based upon what we felt was needed, 22 and it was adjusted as we went along. So 23 that's all I can -- all I can remember. 24 Q. So with respect to this 30-day 25 cumulative algorithm --</p>	<p>1 just as a matter of resources, you would have 2 to tweak that; isn't that correct? 3 A. And I think that's what this is 4 showing here, is we were tweaking things that 5 we felt that we could tweak without losing 6 focus of what we intended to do. 7 And again, we weren't given any 8 guidance on what it should be doing, but we 9 felt we still had a pretty robust system, and 10 just 150 orders were not within our -- our -- 11 able to do that at that time. So we felt by 12 changing this we could still maintain a 13 robust system. 14 Q. But part of what you were 15 looking at in terms of designing this system 16 was its ability to function given the 17 resources that were assigned to it; is that 18 fair? 19 A. I'm not sure if that's fair. 20 We felt we -- we still felt with our end 21 product that we had a good product, and with 22 the resources that we had that we could 23 manage it. 24 Q. Well, with respect to, for 25 example, this 30-day cumulative algorithm, no</p>

<p style="text-align: right;">Page 222</p> <p>1 one ever went back and actually reviewed the 2 orders that were no longer being kicked out 3 because the algorithm was turned off?</p> <p>4 A. I didn't say that. I said I 5 don't remember if somebody did or not.</p> <p>6 Q. Do you feel that analysis 7 should have been done before turning it off?</p> <p>8 A. It probably should have and 9 probably was; I just don't remember.</p> <p>10 Q. And you don't know who would 11 have done that analysis or how it would have 12 been memorialized?</p> <p>13 A. No, I don't.</p> <p>14 Q. Then do you see down it says -- 15 the entry is 4/30/2010?</p> <p>16 A. Yes.</p> <p>17 Q. It says, "Peculiar order 18 calculation change from [REDACTED] times factor to 19 [REDACTED] times factor."</p> <p>20 A. Okay.</p> <p>21 Q. Is that consistent with your 22 recollection of how the algorithm was 23 modified?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. What was the basis for</p>	<p style="text-align: right;">Page 224</p> <p>1 that would have been kicked out under the [REDACTED] 2 times that were not kicked out under [REDACTED] 3 times; is that correct?</p> <p>4 A. That's true.</p> <p>5 Q. Was there ever a trial run or 6 an analysis done to confirm that those orders 7 were not in fact peculiar?</p> <p>8 A. On the ones that didn't kick 9 out?</p> <p>10 Q. Yes, on the ones that were no 11 longer kicked out because of this 12 programmatic change.</p> <p>13 A. I don't remember. I don't know 14 if we did or not.</p> <p>15 Q. Okay. But you believe that is 16 an analysis that should have been done; is 17 that correct?</p> <p>18 A. We probably did it, yes, but I 19 don't remember exactly who did it or when it 20 was done.</p> <p>21 Q. Now, one of the things about 22 increasing the factor from [REDACTED] times to [REDACTED] 23 times is that it does -- it does -- well, 24 strike that.</p> <p>25 Do you recall Ms. Stewart's</p>
<p style="text-align: right;">Page 223</p> <p>1 changing it from [REDACTED] times to [REDACTED] times?</p> <p>2 A. This -- the system had been 3 implemented already. I believe it was the 4 fall of 2009, right?</p> <p>5 Q. I believe that's what you said.</p> <p>6 A. Yeah.</p> <p>7 So after months of working with 8 it and not finding any peculiar orders became 9 suspicious orders, we felt pretty -- pretty 10 good about changing the number from [REDACTED] to [REDACTED] 11 So that's what we did.</p> <p>12 And we ran that -- I ran that 13 by Karen Harper, and Karen Harper agreed to 14 that based upon us not having any suspicious 15 orders, and we put that in place.</p> <p>16 Q. And -- well, why [REDACTED] times 17 instead of [REDACTED] times or [REDACTED] times?</p> <p>18 A. That's the number that we came 19 up with.</p> <p>20 Q. And so sort of going back to a 21 previous question that I've asked.</p> <p>22 A. Uh-huh.</p> <p>23 Q. With respect to the change from 24 [REDACTED] times to [REDACTED] times, you know, 25 presumably there are now orders that are --</p>	<p style="text-align: right;">Page 225</p> <p>1 concern about a gradual -- gradual increases 2 that was referenced on page 3 of this 3 document?</p> <p>4 A. Yes, I remember. Yes.</p> <p>5 Q. Okay. So when you go from a 6 [REDACTED] times to a [REDACTED] times factor, that is 7 going to increase that concern or that risk, 8 isn't it?</p> <p>9 A. I -- yes.</p> <p>10 Q. Okay. And so in this regard, 11 with respect to this risk, meaning a gradual 12 increase over time, this calculation is now 13 less protective than it would have been if it 14 were two times?</p> <p>15 A. That's -- that's true. But 16 keep in mind, we were not -- we were not 17 the -- selling to the end user in that. Not 18 only were we -- we weren't -- we were selling 19 this material to the distributors and -- who 20 had their own programs in place, and they 21 were also responsible for reviewing the 22 orders and customers that they were selling 23 to.</p> <p>24 So we felt even with the [REDACTED] 25 where we weren't finding any issues with</p>

<p style="text-align: right;">Page 226</p> <p>1 orders that we couldn't explain, and we -- we 2 changed our process to the █ and continued 3 to monitor. And we changed it to █, and we 4 still didn't have any peculiar orders that 5 became suspicious orders.</p> <p>6 Q. Well, by --</p> <p>7 A. But we felt comfortable in 8 doing this at the time.</p> <p>9 Q. By changing the formula from 10 █ to █</p> <p>11 A. Right. And we discussed that, 12 yes.</p> <p>13 Q. Yes.</p> <p>14 And it would -- it would -- I 15 mean, well, one of the effects is that it 16 decreased the number of orders you were 17 reviewing, yes?</p> <p>18 A. That's true.</p> <p>19 Q. Do you recall how much of a 20 decrease this was?</p> <p>21 A. I don't -- I don't remember.</p> <p>22 Q. Now, you indicated in your 23 prior answer that -- well, strike that.</p> <p>24 Is it fair to say that part of 25 the reason Mallinckrodt was comfortable</p>	<p style="text-align: right;">Page 228</p> <p>1 attention to page 7 of this memo, you see at 2 the very bottom of the page it says, "Action 3 plan"?</p> <p>4 A. Okay.</p> <p>5 Q. And in the middle of that 6 paragraph at the very bottom it says, "The 7 team believes the suspicious order monitoring 8 program can be further enhanced by analyzing 9 chargeback data for indirect customers and 10 direct sales information available within 11 existing systems."</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. Do you know if the suspicious 15 order monitoring program was ever modified to 16 take -- to analyze chargeback data?</p> <p>17 A. Yes, it was. As part of our 18 ongoing enhancement program for the 19 suspicious order program, it was identified 20 that the chargeback system could help us in 21 identifying who the distributors were selling 22 to. So eventually in 2010, this was -- the 23 monitoring of suspicious orders were moved 24 over to the chargeback team.</p> <p>25 Q. And do you recall when in 2010</p>
<p style="text-align: right;">Page 227</p> <p>1 making this change from █ to █ is 2 because, as you indicated, the distributors 3 have their own programs for suspicious 4 orders?</p> <p>5 A. Well, that was part of it.</p> <p>6 Part of it was that we had not found any 7 peculiar orders that became suspicious 8 orders. And as we changed it to █ and we 9 had approval to do that, or I had approval to 10 do that, we continued to monitor orders, 11 peculiar orders, and again, we did not have 12 any suspicious orders.</p> <p>13 Q. What did you do to -- well, 14 what did Mallinckrodt do to satisfy -- 15 satisfy itself that the distributors were 16 implementing adequate SOM programs?</p> <p>17 A. I wasn't -- I was just there at 18 the beginning of this, but -- I should say, 19 actually it probably started in 2009, but 20 there was a team that was put together of 21 Karen Harper and one of the legal people 22 along with -- who would do audits with the 23 distributors to see what programs they had in 24 place.</p> <p>25 Q. Now, if I could direct your</p>	<p style="text-align: right;">Page 229</p> <p>1 this occurred?</p> <p>2 A. Fall of 2010.</p> <p>3 Q. And so were you still involved 4 in the suspicious order monitoring program at 5 that point?</p> <p>6 A. The daily review was turned 7 over to that department.</p> <p>8 Q. So what you had previously 9 described about how you would get 50 orders 10 and then you would contact the --</p> <p>11 A. Right.</p> <p>12 Q. -- sales reps, that was no 13 longer your responsibility?</p> <p>14 A. Correct. It was turned over to 15 this other group that had the chargeback 16 information.</p> <p>17 Q. Okay. And do you know who in 18 this other group it was turned over to?</p> <p>19 A. Tiffany is who I had mentioned 20 earlier. I don't remember her last name.</p> <p>21 Q. Okay. And do you know what 22 procedure or process she followed?</p> <p>23 A. No, I don't.</p> <p>24 Q. Do you know if she continued to 25 review these reports on a daily basis?</p>

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	<p>1 A. I believe she did, yes.</p> <p>2 Q. And she continued to</p> <p>3 communicate with the sales reps?</p> <p>4 A. I would imagine that would be</p> <p>5 part of her process. I'm not sure what she</p> <p>6 did once she took over it, but I explained to</p> <p>7 her what I did and -- as far as what my</p> <p>8 review -- what review I took as far as</p> <p>9 talking to the sales reps and the business</p> <p>10 managers. And they also had the chargeback</p> <p>11 system in that group, so I'm sure it was used</p> <p>12 to enhance the system.</p> <p>13 Q. And you indicated that --</p> <p>14 A. And I turned over all my files</p> <p>15 over to her -- for her, to her group.</p> <p>16 Q. And do you know how she used</p> <p>17 the chargeback data?</p> <p>18 A. I don't.</p> <p>19 Q. Now, prior to 2010, did you</p> <p>20 have access to the chargeback data?</p> <p>21 A. I did not, no.</p> <p>22 I think it was identified as a</p> <p>23 source that we could implement to enhance our</p> <p>24 system as we were looking for opportunities</p> <p>25 for more information and that. That was</p>	<p>1 QUESTIONS BY MR. KAWAMOTO:</p> <p>2 Q. So I'm marking another exhibit.</p> <p>3 It is Exhibit 8.</p> <p>4 A. Are we done with this one?</p> <p>5 Q. Yes, we're done with that one.</p> <p>6 And this has Bates number</p> <p>7 MNK-T1_264431.</p> <p>8 A. Okay.</p> <p>9 Q. Okay. Now, just as a matter of</p> <p>10 chronology, the enhanced -- the enhanced SOM</p> <p>11 program came online in 2000 -- in the fall</p> <p>12 of 2009?</p> <p>13 A. Yes.</p> <p>14 Q. And in fall of 2010, your SOM</p> <p>15 responsibilities were transferred to Tiffany?</p> <p>16 A. That's correct.</p> <p>17 Q. So you oversaw the enhanced SOM</p> <p>18 program for dosage products for one year?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. This document, it's</p> <p>21 Bates-numbered MNK-10-1_264431 {sic}, and it</p> <p>22 purports to describe the peculiar order</p> <p>23 process.</p> <p>24 A. Okay.</p> <p>25 Q. Based on your review, does this</p>
	<p>1 pointed out as, hey, maybe we can use the</p> <p>2 chargeback system.</p> <p>3 Q. Well, how old is the chargeback</p> <p>4 system?</p> <p>5 A. It's been around for a long</p> <p>6 time.</p> <p>7 Q. So in 2008 and 2009, you had</p> <p>8 chargeback data; is that correct?</p> <p>9 A. We did.</p> <p>10 Q. And so in -- so in theory, one</p> <p>11 could have used this chargeback data, you</p> <p>12 know, in 2007 or 2008 or 2009?</p> <p>13 A. In theory it could have.</p> <p>14 Q. So it's not as if Mallinckrodt</p> <p>15 was collecting now data starting in 2010; it</p> <p>16 was that it was using the data it had?</p> <p>17 A. Yes, and we -- I don't remember</p> <p>18 exactly how we -- you know, we finally</p> <p>19 figured out, hey, maybe we can start, you</p> <p>20 know, digging deeper into the -- into who our</p> <p>21 customers were selling to also as part of an</p> <p>22 enhancement.</p> <p>23 (Mallinckrodt-Rausch Exhibit 8</p> <p>24 marked for identification.)</p>	<p>1 accurately describe what Mallinckrodt's</p> <p>2 peculiar order process was from fall of 2009</p> <p>3 to fall of 2010?</p> <p>4 A. As -- as a peculiar order, yes.</p> <p>5 Q. Okay. And then you'll note</p> <p>6 that someone --</p> <p>7 A. This is what I was trying to</p> <p>8 describe to you earlier but probably didn't</p> <p>9 do a very good job of it, where it summarizes</p> <p>10 the API of the product.</p> <p>11 Q. Okay. And you'll see how</p> <p>12 the -- in the peculiar order criteria, the █</p> <p>13 has been crossed out and someone has</p> <p>14 substituted █ in there.</p> <p>15 A. Okay.</p> <p>16 Q. So this would suggest that this</p> <p>17 document was -- would have been prepared</p> <p>18 sometime in 2010, because that's when that</p> <p>19 decision was made?</p> <p>20 A. Sometime in that time frame,</p> <p>21 yes.</p> <p>22 Q. Okay. Now, it says, "New</p> <p>23 customers for dosage. Dosage will manually</p> <p>24 establish the threshold limit."</p> <p>25 What -- what is the threshold</p>

<p style="text-align: right;">Page 234</p> <p>1 limit?</p> <p>2 A. I believe the threshold limit, 3 if I remember right, was based upon the 4 customer class of what the average order 5 amount was for that -- a customer of that 6 type.</p> <p>7 Since we had no previous orders 8 from this customer, we -- we just took the 9 average of what we were selling to customers 10 like -- like them so we had some kind of 11 basis to go on.</p> <p>12 Q. And when you say "customer 13 class," what do you mean by that?</p> <p>14 A. Like distributor.</p> <p>15 Q. So distributor verse wholesaler 16 verse chain pharmacy, are those the different 17 classes?</p> <p>18 A. I would say so, yes.</p> <p>19 Q. And the threshold limit is 20 essentially -- it's the base that the 21 algorithm would compare the current order to 22 sort of the historic baseline; is that 23 accurate?</p> <p>24 A. Yes.</p> <p>25 Q. So for the threshold -- well,</p>	<p style="text-align: right;">Page 236</p> <p>1 that we already had on the books and get an 2 average based upon that as our criteria to 3 start with.</p> <p>4 Q. Okay. So it sounds like you 5 had distributor subclasses, essentially?</p> <p>6 A. Yes.</p> <p>7 (Mallinckrodt-Rausch Exhibit 9 8 marked for identification.)</p> <p>9 QUESTIONS BY MR. KAWAMOTO:</p> <p>10 Q. Okay. So I'd like to mark as 11 Exhibit 9 the following document, and this 12 has a Bates number MNK-T1_269399.</p> <p>13 A. Okay.</p> <p>14 Q. Okay. So this is a memo dated 15 November 2, 2010, to Karen Harper from Howard 16 Davis.</p> <p>17 A. Okay.</p> <p>18 Q. Do you know who Howard Davis 19 is?</p> <p>20 A. I believe he was with the DEA.</p> <p>21 Q. Okay. And did you ever work 22 with Howard Davis on anything while you were 23 at Mallinckrodt?</p> <p>24 A. No, I didn't. Not that I 25 remember.</p>
<p style="text-align: right;">Page 235</p> <p>1 strike that.</p> <p>2 So one of the problems could be 3 if your threshold limit were set too high, 4 then, you know, orders that should be tagged 5 as peculiar would not be; is that fair?</p> <p>6 A. That's possible.</p> <p>7 Q. All right. Now, you indicated 8 that the threshold limit was set based on the 9 average of all of the distributors.</p> <p>10 A. I believe so. I think that's 11 how it was done, yes.</p> <p>12 Q. And for the distributors, was 13 this -- was this average set on an 14 industry-wide assessment of distributors, or 15 was it just Mallinckrodt's distributor 16 customers?</p> <p>17 A. Mallinckrodt's.</p> <p>18 Q. Okay. Now, distributors varied 19 in size and geographic scope, didn't they?</p> <p>20 A. I think we tried to take in 21 effect how many -- how many different 22 distributing warehouses they had, what their 23 typical sales were, that type of thing, all 24 the information that we could gather, and 25 tried to make them comparable to customers</p>	<p style="text-align: right;">Page 237</p> <p>1 Q. Okay. Do you know anything 2 about Howard Davis other than he was with the 3 DEA?</p> <p>4 A. No.</p> <p>5 Q. Okay. So in this memo he 6 states -- well, let's start with the second 7 full paragraph.</p> <p>8 A. Okay.</p> <p>9 Q. He states, "Federal register 10 notices published as early as 2007 state 11 specifically that using formulas that rely on 12 percentages or averages over time has been 13 determined by the DEA to be insufficient." 14 Do you agree with that 15 statement?</p> <p>16 A. Yes.</p> <p>17 Q. Then skipping to the paragraph 18 below that, it says, "An order must not be 19 processed and filled if it's either 20 suspicious or excessive. The existing SOP 21 excels to meet this requirement through a 22 specific evaluation process; however, the 23 numeric formula is problematic. For example, 24 should an occasion arise where an order is 25 [REDACTED] over the historical average for</p>

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<p>1 that customer, an item, or in a situation 2 where the order meets but does not exceed the 3 three times criteria, it would theoretically 4 be filled through normal processing without 5 question -- without further question. In 6 doing so in certain cases and as noted in 7 recent immediate suspensions of other 8 large-scale DEA registrants, which are all a 9 matter of public record, Mallinckrodt would 10 be unnecessarily exposing itself to potential 11 liability."</p> <p>12 Do you see that paragraph?</p> <p>13 A. I do.</p> <p>14 Q. Do you agree with that 15 statement?</p> <p>16 MR. TSAI: Object to the form.</p> <p>17 THE WITNESS: I understand -- I 18 hear -- I hear what he's saying, yes.</p> <p>19 QUESTIONS BY MR. KAWAMOTO:</p> <p>20 Q. Well, and do you agree with his 21 assessment?</p> <p>22 A. Well, we -- we felt that we 23 were -- we had done with the [REDACTED] that we 24 didn't -- as I told you before, we felt 25 comfortable with going from [REDACTED] to [REDACTED] and I</p>	<p>1 A. We wouldn't -- we wouldn't have 2 changed it.</p> <p>3 Q. Okay.</p> <p>4 A. Keep in mind, we were -- you 5 know, we were on our own as far as developing 6 our programs. So, you know, Karen, on doing 7 her job as compliance manager, felt it was 8 important to keep the DEA in the progress of 9 our program that we had placed.</p> <p>10 And I guess in seeing this -- 11 and this is the first time I have seen it -- 12 she apparently brought it to Howard's 13 attention that we had changed from [REDACTED] to 14 [REDACTED] and he apparently responded in this 15 manner.</p> <p>16 Q. Okay. Now, turning to the 17 second page, it says, "Numeric formulas do 18 not identify circumstances that might be 19 indicative of diversion, such as ordering 20 larger quantities of a limited variety 21 regularly that would not otherwise be viewed 22 as suspicious, like ordering controlled 23 substances with few, if any, other drugs or 24 products, whether controlled or 25 noncontrolled, ordering highly abused</p>
<p>Page 239</p> <p>1 had Karen's approval. And apparently in due 2 diligence she talked to Howard Davis about 3 it, and in doing so, he was coming back 4 feeling that going from [REDACTED] to [REDACTED] would 5 be -- expose us to potential liability.</p> <p>6 Q. Did you know that Karen Harper 7 talked to Howard Davis about the [REDACTED] to [REDACTED] 8 change?</p> <p>9 A. I did not.</p> <p>10 Q. Okay. If you had known that 11 Howard Davis had concerns about this [REDACTED] 12 change, would it have -- well, strike that.</p> <p>13 Did you support the change from 14 [REDACTED] to [REDACTED]</p> <p>15 A. Yes, at the time I did.</p> <p>16 Q. If you had known that Howard 17 Davis had concerns about changing it from [REDACTED] 18 to [REDACTED] would that have mattered to your 19 support?</p> <p>20 A. Of course it would have.</p> <p>21 MR. TSAI: Object to the form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 QUESTIONS BY MR. KAWAMOTO:</p> <p>24 Q. Okay. And how would it have 25 mattered?</p>	<p>Page 241</p> <p>1 controlled substances in limited quantities 2 disproportionate to other orders, or even 3 ordering the same controlled substances from 4 multiple suppliers."</p> <p>5 Do you see that?</p> <p>6 A. I see it.</p> <p>7 Q. And do you agree that these are 8 all problems with numeric formulas?</p> <p>9 A. These are all possibilities, 10 yes.</p> <p>11 Q. Okay. And directing your 12 attention to Exhibit 2, so if you go back to 13 the start of the dep, which was that 2006 DEA 14 letter, these are the factors that the DEA 15 identified in that letter, aren't they?</p> <p>16 A. Are you talking about the 10?</p> <p>17 Q. I'm sorry, let me pull that 18 out.</p> <p>19 Yes. If you look at Exhibit 2, 20 on page 3, Bates number 273565, it's the 21 circumstances that might be indicative of 22 diversion, and it lists out four different 23 things.</p> <p>24 A. Oh. Yes, that's what he's 25 talking about there.</p>

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<p>1 Q. Okay. So these four things 2 match up to the concerns that Howard is 3 expressing? 4 A. Yes. 5 Q. And the DEA expressed these 6 concerns in 2006, didn't they? 7 A. It looks like it, yes. 8 Q. Okay. Then underneath that 9 there's another paragraph that says, "The DEA 10 registrant population as a whole is now 11 required to consider the totality of the 12 circumstances when evaluating an order prior 13 to it being filled." 14 Do you under -- do you agree 15 with that statement? 16 A. Yes. 17 Q. Okay. And underneath that, 18 skipping further down, it says, "While not 19 all-inclusive, recommended customer inquiries 20 may include such factors as," and then this 21 lists one, two, three, four, five, six, seven 22 eight, nine -- nine different bullet points. 23 Do you see those? 24 A. I do. 25 Q. And do you agree that all of</p>	<p>1 yearly basis we were sending it out to 2 our customers asking these questions, 3 or similar questions, asking them if 4 they'd fill it out and send it back to 5 us for us to continue to sell to them. 6 QUESTIONS BY MR. KAWAMOTO: 7 Q. Do you know if any attempt was 8 made to verify the information that the 9 customers were providing in this regard? 10 A. I don't know. 11 Q. Okay. Should that information 12 have been verified given its importance? 13 A. I guess it would be. 14 (Mallinckrodt-Rausch Exhibit 10 15 marked for identification.) 16 QUESTIONS BY MR. KAWAMOTO: 17 Q. Now, this document also has an 18 attachment which I'm going to mark as 19 Exhibit 10, and the Bates number for this 20 attachment is MNK-T1_269401. 21 Now, actually, I'm sorry, if I 22 could interrupt you briefly. 23 So going back to Exhibit 9, 24 this memorandum. 25 A. Okay.</p>
<p>1 these should be recommended customer 2 inquiries? 3 MR. TSAI: Object to the form. 4 THE WITNESS: Let me look -- 5 read them. 6 QUESTIONS BY MR. KAWAMOTO: 7 Q. Sure. 8 A. Okay. 9 Q. Okay. So do you agree that 10 this is all information that should be taken 11 into account? 12 A. I believe this was part of that 13 checklist that was being sent out by the 14 credit department, or CDIG, on a yearly basis 15 for our customers to check whether they were 16 doing that or not. 17 Q. Okay. And so if Mallinckrodt's 18 SOM program was not taking into account this 19 information, you would view that as 20 problematic, would you not? 21 MR. TSAI: Object to the form. 22 THE WITNESS: I would. But 23 like I stated, I believe we were 24 sending this out when new customers 25 were being established. And on a</p>	<p>1 Q. Do you know what steps, if any, 2 were taken to address Mr. Davis' concerns? 3 A. This was written in 4 November 2010, and I was no longer 5 responsible for monitoring the orders. But 6 like I mentioned earlier -- as far as the [REDACTED] 7 and the [REDACTED] Okay? 8 And like I stated earlier, I 9 believe this was part of the checklist that 10 we sent out to our -- our customers from 11 CDIG. 12 Q. But you don't know if anything 13 was actually done to modify the enhanced SOM 14 program to respond to Mr. Davis' concerns? 15 A. I do not. 16 Q. Okay. Okay. So can you -- can 17 you review the MNK -- well, I'm sorry, can 18 you review Exhibit 10? 19 And I don't have detailed 20 questions on all of it, but I do have some 21 questions for you on this document. 22 A. Is there a date on this or -- 23 Q. Well, this was an attachment to 24 the Howard Davis memo, so it would presumably 25 have the same date as the memo.</p>

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	<p>1 A. Same date as the memo?</p> <p>2 Q. Yes.</p> <p>3 A. Okay.</p> <p>4 Q. So November of 2010.</p> <p>5 A. And who is this from?</p> <p>6 Q. Well, actually, if you look</p> <p>7 back at Exhibit 10 {sic}, the very bottom of</p> <p>8 the memo, Mr. Davis says, "I recommend the</p> <p>9 immediate revision of SOP number CS COMP 3.0</p> <p>10 to include additional definitive criteria as</p> <p>11 noted above." And then further down he says,</p> <p>12 "The new draft SOP entitled 'Due Diligence</p> <p>13 Procedures and Monitoring of Controlled</p> <p>14 Substances Sales' is included for</p> <p>15 consideration."</p> <p>16 A. Okay.</p> <p>17 Q. And that's what this document</p> <p>18 is.</p> <p>19 A. Oh, okay. So they were giving</p> <p>20 us information on standard operating</p> <p>21 procedure.</p> <p>22 Q. And if it helps your review, my</p> <p>23 questions relate to sections 4, 5, 7, 8 and 9</p> <p>24 of the memo.</p> <p>25 MR. TSAI: We've been going for</p>	<p>1 Q. So Howard Davis is a -- I</p> <p>2 believe he is a former DEA personnel.</p> <p>3 A. Okay.</p> <p>4 Q. And he was working as a</p> <p>5 consultant for Mallinckrodt.</p> <p>6 A. Oh, okay.</p> <p>7 Q. I'm not -- I'm not positive</p> <p>8 exactly what his status was.</p> <p>9 A. Okay.</p> <p>10 Q. But apparently Ms. Harper asked</p> <p>11 him to review the S -- CS COMP 3.0 procedure,</p> <p>12 and he prepared her this memo --</p> <p>13 A. Okay.</p> <p>14 Q. -- with these recommendations.</p> <p>15 A. Oh, okay.</p> <p>16 Q. So I guess my -- one thing I</p> <p>17 wanted to ask you is that -- does that</p> <p>18 change -- does that change any of your prior</p> <p>19 testimony regarding Mr. Davis' views as he</p> <p>20 expressed in his memo?</p> <p>21 MR. TSAI: And I would like to</p> <p>22 object for the record that that line</p> <p>23 of questioning was -- didn't have that</p> <p>24 clarification. And if we're just</p> <p>25 clarifying the record, I think at this</p>
	<p style="text-align: center;">Page 247</p> <p>1 about an hour. Is this a good time to</p> <p>2 take a break since this is a long</p> <p>3 document?</p> <p>4 MR. KAWAMOTO: Well -- okay.</p> <p>5 Well -- sure. Well, why don't I --</p> <p>6 THE WITNESS: I'm willing to</p> <p>7 go.</p> <p>8 MR. KAWAMOTO: Okay. Well,</p> <p>9 yeah -- well, why don't we keep going,</p> <p>10 and if for whatever reason you want to</p> <p>11 take a break, just let me know and I'm</p> <p>12 happy to take a break.</p> <p>13 THE WITNESS: Okay.</p> <p>14 QUESTIONS BY MR. KAWAMOTO:</p> <p>15 Q. So did you want to review some</p> <p>16 more, or should I just ask you questions?</p> <p>17 A. No, go ahead. I mean, I can</p> <p>18 look at it to --</p> <p>19 Q. Okay. So Section 4 is an</p> <p>20 affidavit requirement.</p> <p>21 A. Now, if I'm reading this right,</p> <p>22 this is from the DEA, I believe you said?</p> <p>23 Q. Well, no, that is something I</p> <p>24 wanted to clarify with you.</p> <p>25 A. Okay.</p>	<p style="text-align: center;">Page 249</p> <p>1 time when Exhibit 9 was written,</p> <p>2 Howard Davis was not speaking on</p> <p>3 behalf of the DEA or employed by the</p> <p>4 DEA.</p> <p>5 QUESTIONS BY MR. KAWAMOTO:</p> <p>6 Q. So with that -- with that</p> <p>7 clarification --</p> <p>8 A. Okay.</p> <p>9 Q. -- does that change your</p> <p>10 opinion of any of the views he's expressing</p> <p>11 in his memorandum?</p> <p>12 A. Does it change my opinion?</p> <p>13 What in particular did you want</p> <p>14 to talk about? 4 or the whole thing or --</p> <p>15 Q. Well, no, let's go back --</p> <p>16 let's go back. I didn't realize that --</p> <p>17 until I reviewed the transcript, I didn't</p> <p>18 realize there was that confusion.</p> <p>19 But going back to Exhibit 9 --</p> <p>20 A. So this was written by someone</p> <p>21 that I guess -- that we had -- that was a</p> <p>22 former DEA employee that we had consulted</p> <p>23 with to go over the -- our process --</p> <p>24 Q. Yes.</p> <p>25 A. -- and make recommendations?</p>

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<p>1 Q. That is my understanding.</p> <p>2 Well, you, I believe -- based on this memo,</p> <p>3 it appears you asked him to review the</p> <p>4 program.</p> <p>5 A. When you say "you" --</p> <p>6 Q. I believe Karen Harper.</p> <p>7 A. -- Karen Harper did.</p> <p>8 Q. Yes.</p> <p>9 A. Okay. So I just want to</p> <p>10 establish that this is something that Karen</p> <p>11 Harper had asked him to review and reported</p> <p>12 it back to him. This is the first time I've</p> <p>13 seen this document, so --</p> <p>14 MR. TSAI: And again, I'll</p> <p>15 object for the record to that line of</p> <p>16 questioning and testimony, given the</p> <p>17 misunderstanding that was just put on</p> <p>18 the record.</p> <p>19 QUESTIONS BY MR. KAWAMOTO:</p> <p>20 Q. Well, okay. In that case, why</p> <p>21 don't we turn to Exhibit 9. So can you pick</p> <p>22 up Exhibit 9 again?</p> <p>23 A. Okay.</p> <p>24 Q. So this -- this is -- this is</p> <p>25 the memo that Mr. Davis prepared for</p>	<p>1 paragraph.</p> <p>2 A. Okay. Yes, I would agree with</p> <p>3 that.</p> <p>4 Q. Okay. And the statement that</p> <p>5 "an order must not be processed and filled if</p> <p>6 it is either suspicious or excessive," you</p> <p>7 would agree with that statement?</p> <p>8 A. Okay.</p> <p>9 Q. Well, I'm sorry, so --</p> <p>10 A. I'm just seeing now, he's</p> <p>11 reviewing -- this is a review and -- of -- by</p> <p>12 Howard Davis. And he's -- he's telling Karen</p> <p>13 that right now, as the -- the current process</p> <p>14 is being done is that we have time frame --</p> <p>15 or we decided that we could allow an order</p> <p>16 determined as peculiar to go ahead and ship</p> <p>17 as long as we continued to do our due process</p> <p>18 of following up on the order to make sure it</p> <p>19 was not becoming a suspicious order -- not a</p> <p>20 suspicious order.</p> <p>21 So I think that's what he's</p> <p>22 addressing.</p> <p>23 Q. Okay.</p> <p>24 A. Addressing here.</p> <p>25 Then he goes on to address the</p>
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<p>1 Ms. Harper?</p> <p>2 A. Oh, okay.</p> <p>3 Q. Okay?</p> <p>4 A. Okay. So that makes it a</p> <p>5 little more clear that he wasn't working for</p> <p>6 the DEA.</p> <p>7 Q. He was not working for the DEA,</p> <p>8 though he was formerly employed by them and</p> <p>9 presumably had some expertise.</p> <p>10 A. Right. And he had -- Karen had</p> <p>11 asked him to review our process.</p> <p>12 Q. Yes.</p> <p>13 A. Okay.</p> <p>14 Q. And so when he says, "Federal</p> <p>15 register notices published as early as 2007</p> <p>16 state specifically that using formulas that</p> <p>17 rely on percentages or averages over time has</p> <p>18 been determined by the DEA to be</p> <p>19 insufficient," would you agree with that</p> <p>20 statement?</p> <p>21 MR. TSAI: Object to the form.</p> <p>22 THE WITNESS: Where are you at?</p> <p>23 I'm sorry.</p> <p>24 QUESTIONS BY MR. KAWAMOTO:</p> <p>25 Q. The middle of the second</p>	<p>1 other portion of what was in place at the</p> <p>2 time, that we changed it from █ to █</p> <p>3 Q. Uh-huh.</p> <p>4 A. Okay? And he brought this up</p> <p>5 as some concerns that he may have that we</p> <p>6 might want to address.</p> <p>7 Q. Okay. And so the statement he</p> <p>8 has when "an order must not be processed and</p> <p>9 filled if it is either suspicious or</p> <p>10 excessive," do you agree with that statement?</p> <p>11 Is he correct on that point?</p> <p>12 A. I agree with what he is coming</p> <p>13 back and telling us, that it should not be</p> <p>14 shipped, okay?</p> <p>15 And what I'm saying, as part of</p> <p>16 our daily review prior to this, prior to</p> <p>17 Howard Davis saying this, that we were going</p> <p>18 ahead if the order was peculiar and we were</p> <p>19 not able to completely vet the order -- and</p> <p>20 what I mean by that is, as the sales</p> <p>21 department or the salesmen or the marketing</p> <p>22 person in a due fashion of time, that we</p> <p>23 would go ahead and allow the order to ship,</p> <p>24 and we would continue the process of</p> <p>25 evaluating whether it should be moved to a</p>

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<p>1 suspicious order.</p> <p>2 So he's coming back after</p> <p>3 review and saying, "This is something that</p> <p>4 you may want to not -- may not want to do."</p> <p>5 Q. Okay. And do you agree with</p> <p>6 his assessment, that that is something that</p> <p>7 you don't want to do?</p> <p>8 A. Well, at the time I don't -- I</p> <p>9 didn't agree with it. I felt that we -- we</p> <p>10 were doing our -- our job, and we had a</p> <p>11 six-month or five-month history of working at</p> <p>12 two months and not having an order that</p> <p>13 became -- went from peculiar to suspicious,</p> <p>14 and we felt it was okay based upon that to</p> <p>15 move it to three times. All right? So we</p> <p>16 felt that was okay. Karen approved.</p> <p>17 And Howard came back, from what</p> <p>18 I'm reading here, and saying that you may</p> <p>19 want to change that. That's what I get out</p> <p>20 of it.</p> <p>21 Q. Well, actually, what he's</p> <p>22 saying, if you just read the text, is, "An</p> <p>23 order must not be processed and filled if it</p> <p>24 is either suspicious or excessive."</p> <p>25 So do you disagree with that</p>	<p>1 matter of public record, Mallinckrodt would</p> <p>2 be unnecessarily exposing itself to potential</p> <p>3 liability."</p> <p>4 A. Okay.</p> <p>5 Q. Do you see that statement?</p> <p>6 A. I do.</p> <p>7 Q. Do you agree with that, sir?</p> <p>8 MR. TSAI: Object to the form.</p> <p>9 THE WITNESS: I guess all I can</p> <p>10 say is that we felt that we could do</p> <p>11 that. And Howard, who was a former</p> <p>12 employee of the DEA, is saying as a</p> <p>13 consultant that you may want to relook</p> <p>14 at your -- and that's what Karen was</p> <p>15 doing, was asking him to review what</p> <p>16 we were doing and pointing out things</p> <p>17 that he felt that we might be liable</p> <p>18 for.</p> <p>19 So in that case he's saying,</p> <p>20 you may want to review your [REDACTED] -- or</p> <p>21 your [REDACTED] program and change it to [REDACTED]</p> <p>22 because the potential for orders going</p> <p>23 through you might be liable for.</p> <p>24 QUESTIONS BY MR. KAWAMOTO:</p> <p>25 Q. And had How -- had you known</p>
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<p>1 statement?</p> <p>2 Can an order be processed and</p> <p>3 filled if it is suspicious or excessive?</p> <p>4 A. Well, it shouldn't if it's</p> <p>5 deemed suspicious.</p> <p>6 Q. Okay. So if an order is -- if</p> <p>7 an order is either suspicious or excessive,</p> <p>8 it should not be processed and filled; is</p> <p>9 that fair?</p> <p>10 A. That's what he's saying, yes, I</p> <p>11 agree with that.</p> <p>12 Q. Then he goes on to say, "The</p> <p>13 existing SOP excels to meet this requirement</p> <p>14 through a specific evaluation process.</p> <p>15 However, the numeric formula is problematic.</p> <p>16 For example, should an occasion arise where</p> <p>17 an order is three times over the historical</p> <p>18 average for that customer and item, or in a</p> <p>19 situation where the order meets but does not</p> <p>20 exceed the three times criteria, it would</p> <p>21 theoretically be filled through normal</p> <p>22 processing without further question. In</p> <p>23 doing so, in certain cases and as noted in</p> <p>24 recent immediate suspensions of other</p> <p>25 large-scale DEA registrants, which are all a</p>	<p>1 that Howard had this concern, would you still</p> <p>2 have supported a change from the [REDACTED] to [REDACTED]</p> <p>3 A. Well, I'm not sure when -- this</p> <p>4 was done in October, I believe.</p> <p>5 Q. Oh, it's November of 2010.</p> <p>6 A. November of 2010. And I</p> <p>7 believe we made that change prior to November</p> <p>8 of 2010. Okay?</p> <p>9 And to answer your question,</p> <p>10 if -- if Howard pointed this out and Karen,</p> <p>11 you know, agreed with him, we would change it</p> <p>12 back to the [REDACTED]</p> <p>13 Q. Well, putting Karen aside</p> <p>14 because --</p> <p>15 A. Right.</p> <p>16 Q. -- you don't know what Karen</p> <p>17 did, you know, after she received this memo,</p> <p>18 correct?</p> <p>19 A. Right.</p> <p>20 Q. So just from the standpoint of</p> <p>21 your support and your -- your support for the</p> <p>22 change from [REDACTED] to [REDACTED] --</p> <p>23 A. Right.</p> <p>24 Q. -- if Mr. Davis had sent this</p> <p>25 memo to you, would it have -- would it have</p>

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<p>1 affected your support for changing the 2 program from [REDACTED] to [REDACTED] 3 MR. TSAI: Object to the form. 4 THE WITNESS: It probably would 5 have. 6 QUESTIONS BY MR. KAWAMOTO: 7 Q. Okay. 8 A. I thought I had answered that, 9 but maybe I'll make it clear. 10 Q. And when you say "it probably 11 would have," would it have made it less 12 likely that you would have supported the [REDACTED] 13 to [REDACTED] change? 14 MR. TSAI: Object to the form. 15 THE WITNESS: If I had known a 16 person who was familiar with the DEA 17 and we had hired to evaluate our 18 program, and he thought that it was -- 19 it was potentially liable to change it 20 from [REDACTED] to [REDACTED] I probably would not 21 have made that change. 22 QUESTIONS BY MR. KAWAMOTO: 23 Q. Okay. Now, flipping to the 24 next page that says, "Numeric formulas do not 25 identify circumstances that might be</p>	<p>1 do to make it better. 2 Q. And what -- I mean, 3 specifically what he's doing here is he's 4 identifying various circumstances that aren't 5 captured by numeric formulas. 6 A. Okay. 7 Q. Would you agree that the four 8 circumstances he's identifying are not 9 captured by numeric formulas? 10 A. The four -- the four of them in 11 that paragraph? 12 Q. Yes, I believe so. 13 A. I'm not -- I'm not sure how we 14 would know or even ordering the same 15 controlled substance from multiple suppliers. 16 I'm not sure how we would know that. 17 Q. Okay. But you would agree, 18 though, that that is a factor that isn't 19 captured by a numeric formula -- 20 A. That's true. 21 Q. -- putting aside the question? 22 Okay. 23 So with respect to these four 24 factors -- well, taking a step back. 25 You would agree that these four</p>
<p>1 indicative of diversion." 2 Do you see that paragraph? 3 A. I'm sorry, say that again? 4 Which paragraph? 5 Q. Sure. It's the top paragraph 6 on page 2 of the memo. 7 A. Okay. 8 Q. It says, "Numeric formulas do 9 not identify circumstances." 10 Do you see that? 11 A. I do. 12 Q. Okay. And it identifies four 13 circumstances that are indicative of 14 diversion that wouldn't be captured by 15 numeric formula. 16 A. Okay. 17 Q. Do you agree with that 18 statement? 19 A. Well, what he's pointing out is 20 maybe things that we could add to our 21 program, and we were, of course, always ready 22 to take input from other resources. 23 I take it that's why we hired 24 Howard, to review our process and see if 25 there was anything that he felt that we could</p>	<p>1 factors might be indicative of diversion; is 2 that fair? 3 MR. TSAI: Object to the form. 4 THE WITNESS: It's possible, 5 yes. 6 QUESTIONS BY MR. KAWAMOTO: 7 Q. Okay. And you would also agree 8 that these four factors are not captured by 9 numeric formula? 10 A. I think that's what he's 11 pointing out, yes. 12 Q. And you would agree with him on 13 that? 14 A. Yes. 15 Q. Okay. And then these four 16 factors were also the same ones indicated by 17 the DEA in September of 2006. This is 18 Exhibit 2. 19 A. Okay. 20 Q. Right. I just wanted to make 21 sure your testimony on that hasn't changed. 22 A. No, it hasn't changed. 23 Q. Okay. And then going to the 24 paragraph underneath the paragraph regarding 25 numeric formulas where it says, "The DEA</p>

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<p>1 registrant population as a whole is now 2 required to consider the totality of the 3 circumstances when evaluating an order prior 4 to it being filled."</p> <p>5 Do you see that statement? 6 A. I do. 7 Q. And you would agree with that, 8 correct? 9 A. I agree. 10 Q. Okay. And then going down to 11 the nine bullet points that Mr. Davis 12 identifies as being important information to 13 gather from customers, you would still agree 14 that that is important information? 15 MR. TSAI: Object to the form. 16 THE WITNESS: I believe this -- 17 yes, they would be important factors. 18 QUESTIONS BY MR. KAWAMOTO: 19 Q. Okay. So putting that document 20 aside and turning now to Exhibit 10. So -- 21 A. I just was reading this last 22 one. 23 Q. Go ahead. 24 A. I wanted to see what he 25 recommended.</p>	<p>1 A. I do. 2 Q. Okay. Do you know if this 3 requirement was ever put in place? 4 A. I believe it was. 5 Q. Okay. 6 A. I believe it was part of the 7 CDIG checklist that was sent out to the 8 customers. 9 Q. Okay. Section 5, which is 10 background documentation. And these are 11 documents by customer type, asking the 12 customer specific questions about their 13 businesses and their licenses. 14 And can you review the various 15 questions? 16 A. Okay. 17 Q. Okay. Do you agree that it 18 makes sense to ask customers these types of 19 questions? 20 MR. TSAI: Object to the form. 21 QUESTIONS BY MR. KAWAMOTO: 22 Q. Well, let me rephrase that. 23 Do you agree that customers 24 should be asked the following questions that 25 he identifies?</p>
<p>1 Okay. 2 Q. Now, turning to -- 3 A. This is the draft that he 4 prepared? 5 Q. Yes, this is the draft that he 6 prepared. This, I believe, is Exhibit 10. 7 A. Okay. 8 Q. So do you see on page -- or 9 Section 4 of this draft it says, "Affidavit"? 10 A. Okay. 11 Q. Okay. 12 A. Okay. 13 Q. Okay. So this -- this is -- 14 Howard is proposing an affidavit requirement, 15 and the affidavit would verify that the 16 customer is not an online pharmacy and has 17 never conducted business as an Internet 18 pharmacy and is otherwise aware of their 19 corresponding responsibility for dispensing 20 controlled substances legitimately. 21 Do you see that? 22 A. I do. 23 Q. Do you think that this 24 requirement makes sense as part of a 25 suspicious order monitoring program?</p>	<p>1 MR. TSAI: Object to the form. 2 THE WITNESS: I guess I agree 3 that these are things that should 4 be -- again, Howard, I guess, was 5 making recommendations, and I believe 6 that I shouldn't -- I shouldn't speak 7 out of turn because I was in customer 8 service. So this would have been part 9 of the CDIG process, so -- but I do 10 agree these are things that we could 11 possibly ask. 12 QUESTIONS BY MR. KAWAMOTO: 13 Q. Okay. And, well, not only 14 could you possibly ask for them, but you 15 would agree that it would be a good idea to 16 ask these questions? 17 MR. TSAI: Object to the form. 18 THE WITNESS: Like I said, it 19 would be a good idea. 20 QUESTIONS BY MR. KAWAMOTO: 21 Q. Okay. Then turning to 22 Section 7, it says "Memos." 23 A. Okay. 24 Q. Okay. Now, do you agree that 25 this would be a good modification to the</p>

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<p>1 suspicious order monitoring program?</p> <p>2 A. I agree that it would enhance</p> <p>3 it, yes.</p> <p>4 Q. Okay. Do you know if this was</p> <p>5 done?</p> <p>6 A. I don't know.</p> <p>7 Q. Okay. Then Section 8 is an</p> <p>8 on-site inspection report. And it says, "If</p> <p>9 a customer is flagged suspicious based on</p> <p>10 their ordering habits or their due diligence</p> <p>11 documents, then the compliance department may</p> <p>12 require that an on-site inspection be</p> <p>13 conducted by a third-party, experienced,</p> <p>14 trained investigator."</p> <p>15 Do you see that section?</p> <p>16 A. Uh-huh, I do.</p> <p>17 Q. Do you think that requirement</p> <p>18 makes sense as an addition to the suspicious</p> <p>19 order monitoring program?</p> <p>20 A. You're asking me as a customer</p> <p>21 service manager if I feel that this is --</p> <p>22 would be important?</p> <p>23 Q. Yes. And as someone that was</p> <p>24 involved in setting up the SOM program, a</p> <p>25 member of the SOM team.</p>	<p>1 location, review documents, inspect the</p> <p>2 customer's facility, observe the customer's</p> <p>3 dispensing and/or examination practices,</p> <p>4 request additional information from the</p> <p>5 customer and complete an inspection report."</p> <p>6 Do you agree that that would</p> <p>7 have been factors that a third-party</p> <p>8 investigator should have looked at?</p> <p>9 MR. TSAI: Object to the form.</p> <p>10 THE WITNESS: It's something</p> <p>11 that could have been done, yes.</p> <p>12 QUESTIONS BY MR. KAWAMOTO:</p> <p>13 Q. Well, I mean -- well, strike</p> <p>14 that.</p> <p>15 Not only could it have been</p> <p>16 done, but it would have enhanced the program,</p> <p>17 would it not?</p> <p>18 A. It would have enhanced any</p> <p>19 program.</p> <p>20 Q. Okay. Do you know if this was</p> <p>21 actually done?</p> <p>22 A. I don't know.</p> <p>23 Q. Okay. Then Section 9 is</p> <p>24 parameters used in defining orders of</p> <p>25 interest.</p>
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<p>1 A. Well, this is -- this is</p> <p>2 enhancements to the SMO {sic} team, and I</p> <p>3 believe -- well, a form of this was done, as</p> <p>4 I explained earlier, where Karen Harper and</p> <p>5 the team were going ahead and making audits</p> <p>6 on -- with customers. So that's as far as I</p> <p>7 know what was implemented as of the time that</p> <p>8 I was there.</p> <p>9 Q. Do you know if Karen -- I</p> <p>10 believe you previously testified that the</p> <p>11 audits were conducted by Karen Harper and --</p> <p>12 A. A team of other individuals.</p> <p>13 I'm not sure who was all on the team. I know</p> <p>14 one of our lawyers were, and there -- I'm not</p> <p>15 sure if they went ahead and got an</p> <p>16 investigator or not.</p> <p>17 Q. Okay. So you don't know if</p> <p>18 they used a third-party, experienced, trained</p> <p>19 investigator?</p> <p>20 A. I don't. I don't.</p> <p>21 Q. Do you think it would have been</p> <p>22 a good idea to do so?</p> <p>23 A. It wouldn't have hurt.</p> <p>24 Q. Okay. It also says, "The</p> <p>25 investigator will visit the customer</p>	<p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. Okay. So orders of unusual</p> <p>4 size would be a parameter that should be used</p> <p>5 in defining an order of interest; is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. What about an order</p> <p>9 deviating substantially from a normal</p> <p>10 pattern?</p> <p>11 A. Yes.</p> <p>12 Q. What about orders of unusual</p> <p>13 frequency?</p> <p>14 A. Yes.</p> <p>15 Q. What about will call orders,</p> <p>16 meaning requested to be picked up?</p> <p>17 A. We didn't -- we didn't allow</p> <p>18 will call orders that I remember in the</p> <p>19 dosage group.</p> <p>20 Q. Okay. What about orders to be</p> <p>21 delivered -- well, so strike that.</p> <p>22 So will call orders then should</p> <p>23 not have been permitted?</p> <p>24 A. I want to say that it wasn't,</p> <p>25 but I can't verify -- say for sure that that</p>

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<p>1 was true. I don't --</p> <p>2 Q. I'm sorry, go ahead.</p> <p>3 A. Go ahead.</p> <p>4 Q. But in your opinion, will call</p> <p>5 orders should not have been permitted?</p> <p>6 A. I would -- I would say that</p> <p>7 that's true.</p> <p>8 Q. Okay. Orders to be delivered</p> <p>9 to a different location, that should also not</p> <p>10 have been permitted?</p> <p>11 A. I agree.</p> <p>12 Q. Okay. Cash orders should not</p> <p>13 have been permitted?</p> <p>14 A. I don't -- yes, I agree.</p> <p>15 Q. And orders placed out of a</p> <p>16 scope of the customer's field of practice,</p> <p>17 that should not have been permitted?</p> <p>18 MR. TSAI: Objection to the</p> <p>19 form.</p> <p>20 THE WITNESS: I'm not sure if I</p> <p>21 understand what he's saying here, "out</p> <p>22 of the scope of the customer's field</p> <p>23 of practice." I'm not sure I know</p> <p>24 what that is.</p> <p>25</p>	<p>1 THE WITNESS: I would say that</p> <p>2 that would be an enhancement, yes.</p> <p>3 QUESTIONS BY MR. KAWAMOTO:</p> <p>4 Q. Okay. And then actually if you</p> <p>5 look -- do you see number 1 below Section 9?</p> <p>6 A. I do.</p> <p>7 Q. It says, "A physician or</p> <p>8 veterinarian orders certain controlled</p> <p>9 substances that are not consistent with a</p> <p>10 type of practice identified by the</p> <p>11 practitioner's licenses."</p> <p>12 So that would, I imagine, be an</p> <p>13 example of an order placed out of a scope of</p> <p>14 a customer's field of practice?</p> <p>15 A. Yes, I would agree with that.</p> <p>16 Q. Okay. And so that is something</p> <p>17 that should have been considered in</p> <p>18 determining whether or not to fill an order;</p> <p>19 is that correct?</p> <p>20 MR. TSAI: Object to the form.</p> <p>21 THE WITNESS: I -- I would</p> <p>22 agree with that other -- other than we</p> <p>23 weren't filling orders from physicians</p> <p>24 or veterinarians. I'm not sure where</p> <p>25 this is coming from.</p>
<p>1 Page 271</p> <p>1 QUESTIONS BY MR. KAWAMOTO:</p> <p>2 Q. Okay. Could he be referencing,</p> <p>3 for example, if you have a customer of a</p> <p>4 distributor that is, you know, in a certain</p> <p>5 practice area and they are prescribing drugs</p> <p>6 that are generally not used by that practice</p> <p>7 area?</p> <p>8 MR. TSAI: Object to the form.</p> <p>9 THE WITNESS: I'm not really</p> <p>10 sure what he's -- what he's saying</p> <p>11 here. I'm not sure if that's -- what</p> <p>12 you're saying is right or not.</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. Okay. And then the next bullet</p> <p>15 point is, "Orders placed for more than one</p> <p>16 controlled substance that are known to be</p> <p>17 taken together, drug combinations, outside of</p> <p>18 normal prescribing and patient treatment</p> <p>19 practices. Such an example may be narcotics</p> <p>20 with benzodiazepines, Soma and sleep aids</p> <p>21 known as narcotic cocktails."</p> <p>22 So do you believe that these</p> <p>23 types of orders should not have -- that these</p> <p>24 types of orders should not have been placed?</p> <p>25 MR. TSAI: Object to the form.</p>	<p>1 Page 273</p> <p>1 QUESTIONS BY MR. KAWAMOTO:</p> <p>2 Q. Okay. So that's all I have on</p> <p>3 that exhibit.</p> <p>4 MR. KAWAMOTO: Rocky, did you</p> <p>5 want to take a break now?</p> <p>6 MR. TSAI: Let's take a break.</p> <p>7 MR. KAWAMOTO: Okay.</p> <p>8 VIDEOGRAPHER: We're going off</p> <p>9 the record at 4:11 p.m.</p> <p>10 (Off the record at 4:11 p.m.)</p> <p>11 VIDEOGRAPHER: We are back on</p> <p>12 the record at 4:31 p.m.</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. Okay. So, Mr. Rausch, the last</p> <p>15 topic I want to cover with you is the</p> <p>16 clearing of suspicious orders. And what I</p> <p>17 mean by that is you had previously indicated</p> <p>18 that you would receive these reports, and</p> <p>19 then you would contact various people</p> <p>20 regarding the justification.</p> <p>21 A. Right.</p> <p>22 Q. And so just so, you know, both</p> <p>23 of us are on the same page as to my</p> <p>24 questions --</p> <p>25 A. Yes.</p>

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<p>1 Q. -- I want to explore that 2 process. 3 A. Okay. 4 Q. Now, would you agree with the 5 statement that it's important to formally 6 document the investigation of a peculiar 7 order, including the hows and whys of the 8 logic that was used to determine that the 9 order was either appropriate or inappropriate 10 to ship? 11 A. I can tell you what we did. 12 Q. Okay. What did you do then? 13 A. Okay. So we would get the 14 reports, and as I had talked earlier, we had 15 several orders on that report that were 16 flagged as peculiar. And I would go down the 17 line, as I had mentioned earlier, and look at 18 why it was kicking out. There was different 19 flags, reasons, that would be checked on why 20 the order would be flagged. So I would take 21 a look at that. 22 And then I would take a look at 23 reports that I had to my disposal and see if 24 there was anything else that I could see 25 that may be why the order had been flagged</p>	<p>1 bears the Bates number MNK-T1_307119. 2 And this is an e-mail exchange 3 between you and, I believe, people in sales 4 regarding a suspicious order and the business 5 justification for it; is that fair? 6 A. Yes. Let me read it here. 7 Q. Okay. 8 A. Okay. This was a bulk 9 customer. 10 Q. Okay. And do you recall 11 sending or receiving these e-mails? 12 A. I do. 13 Q. Okay. So the top e-mail, it's 14 to Bill Ratliff, who is director of security. 15 A. Right. 16 Q. And it says, "See the 17 information below. Sovereign is an 18 established customer that we have dealt with 19 for years. They are a contract manufacturer 20 that may have gotten some new business. Let 21 me know if we need to do anything else." 22 So this e-mail is the -- is a 23 complete report with respect to the 24 justification for shipping this order; is 25 that fair?</p>
<p style="text-align: center;">Page 275</p> <p>1 that would be okay. Okay? 2 If I could not determine 3 through what I had available to me, then I 4 would go to the CSR, then to the business 5 manager and then to the sales force. And I 6 would send out e-mails to the folks, if I 7 needed to, and document that and attach that 8 to the report. Okay? 9 And then this was filed in the 10 file folder for the month. I believe it's 11 for the month. 12 Q. And the documentation of the 13 order with respect to the information you 14 received from either the CSR or the business 15 manager or the sales force, that consisted of 16 whatever they e-mailed in response to you? 17 A. Yes. 18 Q. So there was no formal, 19 separate report or memo that was prepared? 20 A. No. No. 21 (Mallinckrodt-Rausch Exhibit 11 22 marked for identification.) 23 QUESTIONS BY MR. KAWAMOTO: 24 Q. Okay. So I'd like to mark this 25 as Exhibit 11, and it is -- let's see. It</p>	<p style="text-align: center;">Page 277</p> <p>1 A. I'm not sure if it's the 2 complete report. I don't see a response from 3 Bill. 4 Q. Okay. 5 A. So I'm sure there was, you 6 know, continued e-mails on what he -- if he 7 gave his approval or not. 8 Q. Okay. Now, it says they're a 9 contract manufacturer that may have gotten 10 some new business. 11 A. That's -- okay. 12 Q. Do you see the "may"? 13 A. Yes. 14 Q. So that indicates that you 15 weren't sure whether they had gotten new 16 business. You thought they may have? 17 A. That's what Tom Palmer is 18 saying, yes. 19 Q. Okay. So do you know if Tom 20 took any steps to verify that they in fact 21 had new business? 22 A. I cannot tell that from what he 23 put in this e-mail. 24 Q. Okay. Did you take any steps 25 to verify that they in fact had gotten some</p>

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<p>1 new business?</p> <p>2 A. You know, he mentions here that</p> <p>3 both Marilyn and Camille are aware of the</p> <p>4 situation. If he learns any more, he would</p> <p>5 let us know.</p> <p>6 So, you know, without all the</p> <p>7 communication that was involved in this</p> <p>8 e-mail, I can't really answer that question</p> <p>9 because I don't see a response from Bill here</p> <p>10 and any continued communication what</p> <p>11 occurred. So to say if this is complete, I</p> <p>12 would say, no, it is not complete.</p> <p>13 Q. Okay. So do you recall taking</p> <p>14 any additional steps to verify this</p> <p>15 information?</p> <p>16 A. I don't remember. I don't</p> <p>17 remember, to answer your question.</p> <p>18 Q. Okay. You indicate, you say,</p> <p>19 "Bill, let me know if we need to do anything</p> <p>20 else."</p> <p>21 A. Right.</p> <p>22 Q. So if Bill were to say no, then</p> <p>23 I assume this would be the complete record;</p> <p>24 is that correct?</p> <p>25 A. "No" meaning that we should not</p>	<p>1 A. Okay.</p> <p>2 Q. Okay. Do you recall sending</p> <p>3 and receiving this e-mail?</p> <p>4 A. I don't recall, but I -- I'm</p> <p>5 sure -- I'm sure I sent it.</p> <p>6 Q. Okay. And this is an e-mail</p> <p>7 from you to Kate and Kate to you --</p> <p>8 A. Correct.</p> <p>9 Q. -- regarding an oxycodone</p> <p>10 order.</p> <p>11 A. Yes.</p> <p>12 Q. And, you know, you're flagging</p> <p>13 an increase in the order.</p> <p>14 A. Correct.</p> <p>15 Q. And Kate's response is, "Jim,</p> <p>16 we are the secondary with CVS Caremark and</p> <p>17 this product. There is only one other</p> <p>18 supplier in the market, so my guess is that</p> <p>19 they're not able to get it from them and have</p> <p>20 ordered from us."</p> <p>21 A. Okay.</p> <p>22 Q. "I don't think it is too big of</p> <p>23 a reason to be alarmed. Thanks, Kate."</p> <p>24 A. Okay. Kate was the business</p> <p>25 person for the product.</p>
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<p>1 ship it or we would --</p> <p>2 Q. No. If Bill says, no, we don't</p> <p>3 need to do anything else, if Bill approves</p> <p>4 this for shipment, then this is a complete</p> <p>5 record?</p> <p>6 A. I believe so, yes.</p> <p>7 Q. Okay. And you don't recall</p> <p>8 whether Bill said yes or not?</p> <p>9 A. I don't see a response here, so</p> <p>10 I don't remember, no.</p> <p>11 Q. Okay.</p> <p>12 A. This was, you know, not --</p> <p>13 Q. Was it Bill --</p> <p>14 A. Ten years ago.</p> <p>15 Q. Was it Bill's general practice</p> <p>16 to request for more information, or did he</p> <p>17 generally just approve these?</p> <p>18 A. No, he -- he would -- he would</p> <p>19 do -- he would look into it, yes.</p> <p>20 (Mallinckrodt-Rausch Exhibit 12</p> <p>21 marked for identification.)</p> <p>22 QUESTIONS BY MR. KAWAMOTO:</p> <p>23 Q. Okay. So this is another</p> <p>24 exhibit. I'm marking it as Exhibit 12, and</p> <p>25 it bears the Bates number 266788.</p>	<p>1 Q. Okay. And so she's saying it's</p> <p>2 her guess --</p> <p>3 A. Right.</p> <p>4 Q. -- that that's why this is.</p> <p>5 A. Right.</p> <p>6 Q. Do you know if she did anything</p> <p>7 to verify her guess?</p> <p>8 A. I would have probably reached</p> <p>9 out to the salesperson.</p> <p>10 Q. Okay. And who is the</p> <p>11 salesperson?</p> <p>12 A. I don't remember who the</p> <p>13 salesperson was for Caremark at this -- off</p> <p>14 the top of my head, I don't remember who it</p> <p>15 is.</p> <p>16 Q. But you would have taken steps</p> <p>17 to verify Kate's guess?</p> <p>18 A. Yeah, my -- my guess is not</p> <p>19 good enough for allowing this order to go</p> <p>20 out, I don't believe.</p> <p>21 Q. Okay. So this should have been</p> <p>22 verified?</p> <p>23 A. Yes.</p> <p>24 Q. And presumably that</p> <p>25 verification would have been attached to the</p>

<p>1 suspicious order report?</p> <p>2 A. I would have hoped so, yes.</p> <p>3 Q. Okay. And it was your practice</p> <p>4 to attach any verification?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. If this wasn't verified</p> <p>7 and this went out just based on Kate's guess,</p> <p>8 that would -- in your view, that would be a</p> <p>9 problem?</p> <p>10 A. It could be a problem, yes.</p> <p>11 (Mallinckrodt-Rausch Exhibit 13</p> <p>12 marked for identification.)</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. Okay. So this is now</p> <p>15 Exhibit 13, and it's being tagged as MN --</p> <p>16 I'm sorry, bears the Bates number</p> <p>17 MNK-T1_266996.</p> <p>18 A. Okay.</p> <p>19 Q. Okay. So this is another</p> <p>20 e-mail chain between you and Kate</p> <p>21 Muhlenkamp --</p> <p>22 A. All right.</p> <p>23 Q. -- regarding a suspicious</p> <p>24 order. Or I'm sorry, regarding a peculiar</p> <p>25 order. And --</p>	<p>1 it was verified, it would have been</p> <p>2 documented as an e-mail attached to the</p> <p>3 suspicious order report, correct?</p> <p>4 A. It could have been, yes.</p> <p>5 Q. Okay.</p> <p>6 A. Should have been.</p> <p>7 Q. Now, the suspicious order</p> <p>8 report, I believe, is that on Bates</p> <p>9 number 266995?</p> <p>10 A. Is it what? I'm sorry?</p> <p>11 Q. I'm looking at Bates</p> <p>12 number 266995. It's a list of orders.</p> <p>13 A. Okay.</p> <p>14 Q. Is that the suspicious order</p> <p>15 report?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And then behind that, on</p> <p>18 page 266997, that's the actual orders; is</p> <p>19 that correct?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. So, you know, the</p> <p>22 complete --</p> <p>23 A. Is there an order number here?</p> <p>24 Q. Sure.</p> <p>25 A. I'm just seeing if it had the</p>
<p>1 A. Okay.</p> <p>2 Q. -- what she says to you is,</p> <p>3 "Jim, I followed up with Steve Becker."</p> <p>4 Would Steve Becker have been</p> <p>5 the business person?</p> <p>6 A. He would have been the</p> <p>7 salesperson, I believe.</p> <p>8 Q. The salesperson? Okay.</p> <p>9 A. Uh-huh.</p> <p>10 Q. "He noted that Henry Schein had</p> <p>11 recently made changes to their internal</p> <p>12 structure and are now servicing additional</p> <p>13 third-party contracts, chargebacks, which may</p> <p>14 be driving their new demand. He was not</p> <p>15 surprised that they had started ordering.</p> <p>16 Hope this helps."</p> <p>17 Do you know if any steps were</p> <p>18 taken to verify that the internal structure</p> <p>19 was in fact driving the new demand?</p> <p>20 A. I don't remember.</p> <p>21 Q. Okay. Should additional steps</p> <p>22 have been taken to verify that?</p> <p>23 A. It could have been warranted,</p> <p>24 yes.</p> <p>25 Q. Okay. And if -- if, in fact,</p>	<p>1 order number on there.</p> <p>2 I'm seeing whether it</p> <p>3 referenced anything that is quoted in the</p> <p>4 e-mail. I'm trying to see if there's</p> <p>5 anything about 456 bottles on here. I don't</p> <p>6 see that.</p> <p>7 And this is dated -- this is</p> <p>8 dated April 26th, and this report's dated</p> <p>9 4/23.</p> <p>10 I'm trying to see if there's</p> <p>11 something that's -- identifies on this report</p> <p>12 this -- what we were e-mailing about. I see</p> <p>13 Henry Schein, but I don't see the order</p> <p>14 quantity that was talked about.</p> <p>15 It says 456, and I don't see</p> <p>16 that on -- on what's attached here.</p> <p>17 So anyway -- okay. So I'm</p> <p>18 assuming that what's attached here is</p> <p>19 referencing an order that the e-mail is</p> <p>20 talking to.</p> <p>21 Q. Okay. So this -- this e-mail</p> <p>22 then would have been the just -- the complete</p> <p>23 justification for shipping this order?</p> <p>24 A. I believe so.</p> <p>25 Q. Okay. And so no steps were</p>

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<p>1 taken then to verify that in fact the 2 internal structure was what was driving their 3 demand; is that correct?</p> <p>4 A. I imagine this was the end of 5 it, yes.</p> <p>6 Q. Okay. And so this -- okay. 7 Strike that.</p> <p>8 (Mallinckrodt-Rausch Exhibit 14 9 marked for identification.)</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. So I'd like to mark this as 12 Exhibit 14, and it bears a Bates number 13 MNK-T1_266735.</p> <p>14 A. Okay.</p> <p>15 Q. Okay. Now, this is an e-mail 16 exchange between you and Penny Myers. 17 Who is Penny Myers?</p> <p>18 A. She was a business manager.</p> <p>19 Q. Okay. And this is -- do you 20 recall receiving -- well, do you recall 21 sending and receiving these e-mails?</p> <p>22 A. I don't recall it, but I -- I 23 wrote it, so, yes.</p> <p>24 Q. Okay. And you were -- you were 25 asking her about a suspicious order from</p>	<p>1 say, okay, and from what I read here is she's 2 saying, okay, based upon estimates from the 3 customers of how much they'll be purchasing, 4 we offered them a price. Okay?</p> <p>5 If they don't purchase close to 6 that amount, we -- the amount they estimate, 7 we encourage them to do that or their price 8 may be adjusted. Okay?</p> <p>9 So based upon their volume, 10 they -- they would -- you can buy at 11 different tiers, is what I'm assuming this is 12 saying.</p> <p>13 Q. So in other words, if they 14 don't purchase close to their estimated 15 quantity, there's a financial, you know, 16 penalty or consequence that gets attached; is 17 that fair?</p> <p>18 A. We're -- from what I read, it 19 sounds that -- when you say "penalty," no, 20 they're telling us that, okay, based upon the 21 amount that they estimated to be buying from, 22 we quote them a price. Okay? If they don't 23 buy that, then we're probably going to have 24 to increase the price.</p> <p>25 Q. Okay.</p>
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<p>1 HD Smith -- or, I'm sorry, a peculiar order 2 for HD Smith, and Penny indicates to you that 3 the order is due to increased compliance and 4 new pharmacies being added.</p> <p>5 And then you ask her, "What is 6 increased compliance?" and the answer she 7 gives you is above.</p> <p>8 Is this the complete record for 9 the justification of this order?</p> <p>10 A. I don't remember.</p> <p>11 Q. Okay. Now, increased 12 compliance. Now, Penny -- well, strike that.</p> <p>13 You asked her what increased 14 compliance is, and Penny responds, "When we 15 offer a price, we asked for the estimated 16 quantity that they will purchase. If they 17 don't purchase close to the amount they 18 estimated, we encourage them to do that or 19 their price may not remain the same or their 20 VIP provision may change."</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. And what do you understand her 24 to be saying with that?</p> <p>25 A. What I'm understanding her to</p>	<p>1 A. You called it a penalty. We 2 call it -- I wouldn't call it a penalty.</p> <p>3 Q. But it would be fair to say 4 they are getting a less favorable price?</p> <p>5 A. Correct.</p> <p>6 Q. So they have a financial 7 incentive from Mallinckrodt to increase their 8 order; is that fair?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. So in essence, in the 11 context of this e-mail, there is a financial 12 incentive from Mallinckrodt to have this 13 seller essentially put in a peculiar order?</p> <p>14 MR. TSAI: Object to the form.</p> <p>15 THE WITNESS: No, I wouldn't 16 say a peculiar order.</p> <p>17 QUESTIONS BY MR. KAWAMOTO:</p> <p>18 Q. Well, this order was flagged in 19 the system as a peculiar order, was it not?</p> <p>20 A. It was. Okay. So what 21 they're -- what it is is that, okay, the 22 order is more than what they've ordered in 23 the past. The system flagged it. The 24 business manager reached out to the sales -- 25 to the customer -- or came back to Penny and</p>

<p style="text-align: right;">Page 290</p> <p>1 said, "This is the reason why the orders have 2 increased, because we've given them a better 3 price if they buy more." So that was 4 justification for the order.</p> <p>5 Q. Okay. And you don't know if 6 they actually had an increase in demand, 7 right? Well, strike that.</p> <p>8 A. I don't know that.</p> <p>9 Q. There's no indication that they 10 had an increase in demand. They might well 11 be purchasing this additional amount because 12 they don't want to have to pay the increased 13 price?</p> <p>14 A. I don't know. That's 15 speculation. I can't answer that.</p> <p>16 Q. But there's nothing in this 17 e-mail that indicates that they are --</p> <p>18 A. One way or the other.</p> <p>19 Q. Yes.</p> <p>20 Okay. So they are -- according 21 to this e-mail, the reason they're asking for 22 significant -- for significantly more than 23 they previously asked for is because they 24 don't want to have to pay a less favorable 25 price; is that fair?</p>	<p style="text-align: right;">Page 292</p> <p>1 Okay.</p> <p>2 Q. Okay. So this is an e-mail 3 between you and Lisa Lundergan.</p> <p>4 Who is Lisa Lundergan?</p> <p>5 A. I believe she was a business 6 manager.</p> <p>7 Q. Okay. And do you recall 8 sending or receiving these e-mails?</p> <p>9 A. I don't recall it, but I see 10 that I did.</p> <p>11 Q. Okay. And then this -- this 12 involves an order for 44,208 bottles of 13 morphine oral --</p> <p>14 A. Okay.</p> <p>15 Q. -- which was three times more 16 than they had ever placed before, and hence 17 it tripped the algorithm.</p> <p>18 A. Correct.</p> <p>19 Q. And Lisa's response to your 20 question as to why they are placing such an 21 order is, "Yes, we are offering them the 22 remainder of our inventory for morphine oral 23 since it was being discontinued. Thank you 24 for checking."</p> <p>25 A. Okay.</p>
<p style="text-align: right;">Page 291</p> <p>1 A. That's correct.</p> <p>2 But that was -- that was the 3 reason why it hit the peculiar order report, 4 and this was the responses back of why. 5 (Mallinckrodt-Rausch Exhibit 15 6 marked for identification.)</p> <p>7 QUESTIONS BY MR. KAWAMOTO:</p> <p>8 Q. I'm going to mark this document 9 as Exhibit 15, and this is MNK-T1_266730.</p> <p>10 Actually, I'm sorry, I just had 11 one more question on Exhibit 14, the 12 compliance e-mail.</p> <p>13 Could you turn to that again?</p> <p>14 A. I'm sorry, which one?</p> <p>15 Q. The prior one.</p> <p>16 A. This one.</p> <p>17 Q. So I think it's Exhibit 14.</p> <p>18 A. Exhibit 14? Okay.</p> <p>19 Q. So the increased compliance 20 justification, that would have been 21 sufficient to justify shipping the order?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Thank you.</p> <p>24 So now we're on Exhibit 15?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 293</p> <p>1 Q. Would that justification have 2 been sufficient for you to ship this order?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Is it a cause for a 5 concern that -- well, strike that. 6 (Mallinckrodt-Rausch Exhibit 16 7 marked for identification.)</p> <p>8 QUESTIONS BY MR. KAWAMOTO:</p> <p>9 Q. Okay. So this is Exhibit 16 10 now. It bears the Bates number 11 MNK-T1_298447.</p> <p>12 A. Okay.</p> <p>13 Q. So this says, "Cardinal placed 14 a large order for" -- 851501, I believe 15 that's the order number -- "for 16 12,720 bottles" -- I'm sorry, let me take a 17 step back.</p> <p>18 So this is an e-mail between 19 you and Kate Muhlenkamp again?</p> <p>20 A. Correct.</p> <p>21 Q. Do you recall receiving or 22 sending these e-mails?</p> <p>23 A. No.</p> <p>24 Q. Okay. Do you have any reason 25 to doubt that you did send or receive them?</p>

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<p>1 A. No.</p> <p>2 Q. Okay. And so the e-mail -- the</p> <p>3 e-mail from you to Kate is that Cardinal has</p> <p>4 placed an order for 12,720 bottles, and their</p> <p>5 average has been 3,227.</p> <p>6 A. Okay.</p> <p>7 Q. And you wanted to know why</p> <p>8 they're increasing their inventory for these</p> <p>9 two products.</p> <p>10 A. Okay.</p> <p>11 Q. And her response is that she</p> <p>12 has been working with Cardinal to increase</p> <p>13 their inventories.</p> <p>14 A. Correct.</p> <p>15 Q. Okay. Would that have been a</p> <p>16 sufficient justification to ship this order?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Do you know why Kate was</p> <p>19 working with Cardinal to increase their</p> <p>20 inventories?</p> <p>21 A. I don't remember, no.</p> <p>22 Q. Okay. Was it -- was it a</p> <p>23 concern to Mallinckrodt if a distributor was</p> <p>24 accumulating an excessively large inventory</p> <p>25 of opioid products?</p>	<p>1 diversion and that as you referred to</p> <p>2 in -- before, you know, the</p> <p>3 distributors had their own programs in</p> <p>4 place for diversion.</p> <p>5 As you can see from the e-mail,</p> <p>6 we were -- we were doing our part as</p> <p>7 far as checking why the order was</p> <p>8 placed, and in my view, we did our due</p> <p>9 diligence of reaching out to the</p> <p>10 business manager. The business</p> <p>11 manager had asked if -- on our behalf</p> <p>12 if they would take a larger increase</p> <p>13 of this product, and as far as I was</p> <p>14 concerned, that was okay for releasing</p> <p>15 the order.</p> <p>16 QUESTIONS BY MR. KAWAMOTO:</p> <p>17 Q. Do you know if Karen Harper</p> <p>18 signed off on the desire to have Cardinal</p> <p>19 increase their inventories?</p> <p>20 A. I don't know that, no.</p> <p>21 Q. Would this have been a decision</p> <p>22 she should have been involved in?</p> <p>23 A. I'm not sure if she should be</p> <p>24 or not.</p> <p>25 What's your -- what's your --</p>
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<p>1 MR. TSAI: Object to the form.</p> <p>2 THE WITNESS: I think what Kate</p> <p>3 was doing here was that Cardinal --</p> <p>4 well, I shouldn't -- I shouldn't</p> <p>5 speculate. I don't know what -- how</p> <p>6 to answer that.</p> <p>7 It would have been a concern,</p> <p>8 well, our business manager felt that</p> <p>9 it was appropriate that we reached out</p> <p>10 to them and asked them for reasons</p> <p>11 that I can't answer right now, to go</p> <p>12 ahead -- if they would go ahead and</p> <p>13 increase their inventories.</p> <p>14 QUESTIONS BY MR. KAWAMOTO:</p> <p>15 Q. From a diversion control</p> <p>16 standpoint, though, is it a concern when a</p> <p>17 distributor starts accumulating a very large</p> <p>18 inventory of controlled substances?</p> <p>19 MS. YOCUM: Objection to form.</p> <p>20 THE WITNESS: I think we were</p> <p>21 reaching out to them, so it was okay</p> <p>22 with us if they went ahead -- if we</p> <p>23 could ship this to them.</p> <p>24 So, again, we are not the --</p> <p>25 the sole party in this stream of</p>	<p>1 well, okay. Go ahead.</p> <p>2 Q. Well, would -- would you agree</p> <p>3 that it is a concern --</p> <p>4 A. I can't -- I can't answer what</p> <p>5 Kate's thinking was on this or what was going</p> <p>6 on behind the scenes as far as us asking them</p> <p>7 to increase their inventories. Maybe they</p> <p>8 were keeping lower-than-expected inventories.</p> <p>9 Maybe -- I don't know. I can't answer for</p> <p>10 what reasons Kate Muhlenkamp had for asking</p> <p>11 for this.</p> <p>12 Q. Well, I'm not asking for -- I'm</p> <p>13 not asking for your speculation as to what</p> <p>14 Kate was thinking.</p> <p>15 A. Okay, but you're -- okay, go</p> <p>16 ahead.</p> <p>17 Q. What I am asking is, from the</p> <p>18 standpoint of diversion control, is it a</p> <p>19 concern to have distributors accumulating</p> <p>20 large inventories of controlled substances?</p> <p>21 A. If they have -- in my</p> <p>22 viewpoint, if they have the controls in</p> <p>23 place, it would not -- it would not be a</p> <p>24 problem.</p> <p>25 Q. And by "controls in place,"</p>

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<p>1 what do you mean by that?</p> <p>2 A. Suspicious order monitoring</p> <p>3 program.</p> <p>4 (Mallinckrodt-Rausch Exhibit 17</p> <p>5 marked for identification.)</p> <p>6 QUESTIONS BY MR. KAWAMOTO:</p> <p>7 Q. So I'd like to mark this as</p> <p>8 Exhibit 17.</p> <p>9 A. Okay.</p> <p>10 Q. So here's an e-mail from Cheryl</p> <p>11 Nelson to Marc Montgomery and Kate</p> <p>12 Muhlenkamp, and you're cc'd on it.</p> <p>13 A. Correct.</p> <p>14 Q. Do you recall receiving this?</p> <p>15 A. No, but I see that I'm cc'd on</p> <p>16 it, so I would have received it, I guess.</p> <p>17 Q. Okay. And so Cheryl is asking</p> <p>18 Kate and Marc about a shipment that has</p> <p>19 triggered the -- the suspicious order</p> <p>20 algorithm, or the peculiar order algorithm;</p> <p>21 is that correct?</p> <p>22 A. I don't know if it triggered</p> <p>23 it, but from what I recall -- I don't know</p> <p>24 where she's getting "we have experienced</p> <p>25 considerable diversion tampering issues." I</p>	<p>1 regard to this customer at NC?</p> <p>2 A. I don't remember.</p> <p>3 Q. Okay.</p> <p>4 A. Again, I don't think it was</p> <p>5 anything that kicked out as far as being on</p> <p>6 a -- on the peculiar order report. I think</p> <p>7 Cheryl was just reaching out and saying that</p> <p>8 they had already reached the quantity of what</p> <p>9 they could buy, and they were asking if they</p> <p>10 could buy more or whatever. That's what I --</p> <p>11 what I read out of this.</p> <p>12 And she reached out to -- to</p> <p>13 Marc Montgomery, who was the director of</p> <p>14 marketing.</p> <p>15 Q. So this -- and this would have</p> <p>16 been sufficient to allow this shipment to go</p> <p>17 through then?</p> <p>18 A. Yes.</p> <p>19 MR. KAWAMOTO: Okay. So why</p> <p>20 don't we take a very short,</p> <p>21 five-minute break, and I should be</p> <p>22 close to wrapping up.</p> <p>23 VIDEOGRAPHER: We're going off</p> <p>24 the record at 5:06 p.m.</p> <p>25 (Off the record at 5:06 p.m.)</p>
<p style="text-align: center;">Page 299</p> <p>1 don't remember that, if that was the case</p> <p>2 anymore.</p> <p>3 But what they're saying here</p> <p>4 is, there was a shortage, if I remember</p> <p>5 right, of this product, and customers were</p> <p>6 only allowed so much a month based upon</p> <p>7 history, sales history, to them.</p> <p>8 And from what I see here,</p> <p>9 Cheryl was reaching out and asking who</p> <p>10 were -- Kate and Marc, who were doing the</p> <p>11 allocations, if it would be okay to ship them</p> <p>12 material.</p> <p>13 Q. Okay. And so Mark says that</p> <p>14 it's okay, and Kate says that it's okay; is</p> <p>15 that correct?</p> <p>16 A. Okay. Yes.</p> <p>17 Q. So would this order have been</p> <p>18 shipped?</p> <p>19 A. Yes, I would assume it would</p> <p>20 be. I don't -- Kate -- yes, I would assume</p> <p>21 it was, because it's not kicking out on the</p> <p>22 suspicious order program.</p> <p>23 Q. Okay. So no one did any</p> <p>24 follow-up regarding what the considerable</p> <p>25 diversion or tampering issues were with</p>	<p style="text-align: center;">Page 301</p> <p>1 VIDEOGRAPHER: We are back on</p> <p>2 the record at 5:14 p.m.</p> <p>3 MR. KAWAMOTO: Okay.</p> <p>4 Mr. Rausch, thank you for your time.</p> <p>5 I have no further questions.</p> <p>6 THE WITNESS: Okay. Thank you.</p> <p>7 MR. TSAI: So just to clarify,</p> <p>8 in case of redirect, I think I</p> <p>9 probably have five minutes.</p> <p>10 Do you want to do that now, or</p> <p>11 should we do Tennessee first?</p> <p>12 MS. CONWAY: I think</p> <p>13 timing-wise, it should be fine for</p> <p>14 her.</p> <p>15 MR. TSAI: Okay.</p> <p>16 VIDEOGRAPHER: We are going off</p> <p>17 the record at 5:14 p.m.</p> <p>18 (Off the record at 5:14 p.m.)</p> <p>19 VIDEOGRAPHER: We are back on</p> <p>20 the record at 5:15 p.m.</p> <p>21 CROSS-EXAMINATION</p> <p>22 QUESTIONS BY MS. HERZFELD:</p> <p>23 Q. Mr. Rausch, how are you doing</p> <p>24 this evening?</p> <p>25 A. Getting tired.</p>

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<p>1 Q. Getting tired. 2 Okay. You're okay to go for 3 another hour or so? 4 A. Is that what it's going to be? 5 Q. Well, we'll see. 6 But do you feel like you're 7 okay, or do we need to reset this for 8 tomorrow? 9 A. No. 10 Q. Want to go forward now? 11 A. We can go forward. 12 Q. Okay. Great. 13 Well, my name is Tricia 14 Herzfeld, and I am one of the attorneys for 15 the plaintiffs in the Tennessee state 16 litigation known as the Staubus and Dunaway 17 cases in state court in Tennessee.</p> <p>18 MS. HERZFELD: Before I start 19 with my questioning, I just wanted to 20 officially lodge an objection on 21 behalf of my clients that the 22 plaintiffs in the Staubus and the 23 Dunaway matter have not -- they've 24 been cross-noticed in this case but 25 have not been provided documents by</p>	<p>1 and Dunaway have been prejudiced in 2 their ability to prepare for this 3 deposition. 4 Additionally, the Tennessee 5 Drug Dealer Liability Act claims at 6 issue in the Tennessee litigation have 7 different elements and require 8 different discovery and areas of 9 inquiry than the MDL. 10 Also, the Tennessee Rules of 11 Civil Procedure do not place any time 12 restrictions on the length of 13 depositions. The Staubus and Dunaway 14 plaintiffs have requested two hours to 15 depose Mr. Rausch today, in addition 16 to the MDL's deposition time. We 17 requested it nine days before this 18 scheduled deposition, and we're happy 19 that we could work that out with the 20 parties. 21 But regardless, if for some 22 reason there are additional documents 23 that come forward at a later date, we 24 would be moving to redepose Mr. Rausch 25 at that time based on the violations</p>
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<p>1 Mallinckrodt in a timely way, nor in 2 compliance with the order issued out 3 of the MDL. 4 According to that order, 5 Mallinckrodt was required to produce 6 Mr. Rausch's complete and total 7 custodial file by November 2nd, 14 8 days in advance of this noticed 9 deposition. Mallinckrodt continued to 10 produce thousands of Mr. Rausch's 11 custodial documents after 12 November 2nd, finally concluding on 13 November 12, 2018, just a few days 14 before we came here today. 15 As required, 14 days before 16 this deposition Mallinckrodt stated 17 that Mr. Rausch had no 18 Tennessee-specific knowledge. The 19 Staubus and Dunaway plaintiffs aren't 20 sure if that is actually true, if you 21 have no knowledge about Tennessee 22 whatsoever, but we intend to ask you 23 questions about Tennessee, regardless. 24 By failing to abide by the 25 protocol, the plaintiffs in Staubus</p>	<p>1 I've just stated. 2 I'm sure you've got something 3 you'd like to say. 4 MR. TSAI: Yeah. For the 5 record, Mallinckrodt's position is 6 quite different from counsel's 7 recitation, and we reserve our rights 8 accordingly. 9 MS. HERZFELD: Great. 10 MR. TSAI: You can go ahead. 11 QUESTIONS BY MS. HERZFELD: 12 Q. Okay. Mr. Rausch, have you 13 ever been to Tennessee? 14 A. No, I have not. 15 Q. Okay. You haven't been for 16 pleasure or for work? 17 A. I drove through Nashville to go 18 to Florida. 19 Q. Okay. Did you stop? 20 A. No. 21 Q. Okay. Do you know when that 22 was? 23 A. No, not offhand. 24 Q. Since you retired? 25 A. Before I retired.</p>

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<p>1 Q. Okay. Okay. And do you have 2 any friends or family that live in Tennessee? 3 A. No. 4 Q. Okay. And when you left 5 Mallinckrodt, did you have any stock options 6 with Mallinckrodt? 7 A. No. 8 Q. Okay. Have you ever owned any 9 stock in Mallinckrodt? 10 A. Years ago, but they've all been 11 cashed. 12 Q. Okay. And was that part of a 13 compensation package for you? 14 A. It was -- it was part of a 15 management program. 16 Q. Okay. 17 A. The stock options were given at 18 a particular price. They had nothing to do 19 with sales or anything like that. 20 Q. Okay. And what year was that? 21 A. Oh, gosh. This is before 22 probably 2000. 23 Q. Okay. And was it just a 24 one-time thing, or was it kind of year after 25 year?</p>	<p>1 Q. Okay. 2 A. I didn't go out and buy a new 3 house or anything. 4 Q. So you think roughly less than 5 \$ [REDACTED] 6 A. Correct. 7 Q. Okay. Great. 8 Okay. Would you agree with the 9 statement that the opioid crisis seems to be 10 worse in some areas of the country? 11 MR. TSAI: Object to the form. 12 THE WITNESS: Would I agree to 13 that? I don't have that information. 14 QUESTIONS BY MS. HERZFELD: 15 Q. Okay. You said before that you 16 did know -- have some knowledge about the 17 opioid crisis in this country. 18 A. From the news, yes. 19 Q. Okay. And do you have any 20 information about particular regions where 21 the opioid crisis may be worse? 22 A. No, I haven't really followed 23 it since I've been retired. 24 Q. You haven't followed the opioid 25 crisis news at all since you've been retired?</p>
<p style="text-align: center;">Page 307</p> <p>1 A. It was for three or four years, 2 and then they raised the level that they 3 would give stock options, and I was no longer 4 in the program. 5 Q. Okay. When you say "they 6 raised the level" -- 7 A. Of participation, as far as it 8 went from managers up to director level, I 9 believe. 10 Q. And you were at what level? 11 A. Manager. 12 Q. And so they took managers out 13 of the availability? 14 A. Correct. 15 Q. Okay. And how much would you 16 say your stock options were worth when you 17 cashed them in? 18 A. I don't remember anymore. 19 Q. Like 10,000? Hundred thousand? 20 A. Some of them weren't worth 21 anything because the stock dropped. 22 Q. Okay. 23 A. No less than -- probably less 24 [REDACTED] but I'm 25 guessing there.</p>	<p style="text-align: center;">Page 309</p> <p>1 A. Well, I've followed it. I've 2 seen it on the news, but it didn't talk 3 specifically about areas that were of greater 4 concern than others. 5 Q. Okay. Have you read any books 6 about the opioid crisis? 7 A. No. 8 Q. Okay. Have you heard 9 particularly that the opioid crisis is 10 particularly bad in Appalachia? 11 A. No, I have not. 12 Q. Okay. What about West 13 Virginia? 14 A. No. 15 Q. What about Kentucky? 16 A. No. 17 Q. Virginia? 18 A. No. 19 Q. How about Tennessee? 20 A. No. 21 Q. You've never heard anything 22 about the opioid crisis in Tennessee? 23 A. Not that I remember. 24 Q. Okay. What about Florida? Do 25 you know anything about there being an opioid</p>

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<p>1 crisis in Florida?</p> <p>2 A. Back in the -- when I was still</p> <p>3 employed, there was some information about</p> <p>4 Florida. I remember some news about Florida</p> <p>5 being a place of concern for the DEA, yes.</p> <p>6 Q. Okay. And do you know where</p> <p>7 you obtained that information?</p> <p>8 A. From the news.</p> <p>9 Q. Okay. Did you ever obtain that</p> <p>10 information through your employment with</p> <p>11 Mallinckrodt?</p> <p>12 MR. TSAI: Objection to this</p> <p>13 line of questioning. It's not</p> <p>14 Tennessee-specific.</p> <p>15 But go ahead.</p> <p>16 THE WITNESS: Karen Harper, our</p> <p>17 DEA compliance officer, brought it up</p> <p>18 to our attention.</p> <p>19 QUESTIONS BY MS. HERZFELD:</p> <p>20 Q. Okay. And what information did</p> <p>21 she give you?</p> <p>22 A. She just noted that the DEA had</p> <p>23 sent out a bullet that there was some issues</p> <p>24 in Florida.</p> <p>25 Q. Okay. And do you know roughly</p>	<p>1 THE WITNESS: Well, no, I</p> <p>2 didn't say that.</p> <p>3 QUESTIONS BY MS. HERZFELD:</p> <p>4 Q. Oh, okay. I want to make sure</p> <p>5 I understand what you're saying, so correct</p> <p>6 me.</p> <p>7 A. Yes. As I said, it was because</p> <p>8 the DEA was saying that there was increased</p> <p>9 diversion, and they were asking us to enhance</p> <p>10 our programs.</p> <p>11 Q. Okay. So when the DEA was</p> <p>12 saying there was increased diversion, the way</p> <p>13 you took that was decreased diversion all</p> <p>14 over the country, but you knew specifically</p> <p>15 about issues in Florida?</p> <p>16 A. Yes, there was bullet put out</p> <p>17 by the DEA to our DEA compliance people, and</p> <p>18 they passed on information about that.</p> <p>19 Q. Okay. So you received specific</p> <p>20 information about Florida?</p> <p>21 A. From what I remember, yes.</p> <p>22 Q. Do you remember any other</p> <p>23 states?</p> <p>24 A. I don't.</p> <p>25 Q. Okay. Were you aware that</p>
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<p>1 what year that was?</p> <p>2 A. I'd be guessing. I don't know.</p> <p>3 Probably -- I'd be guessing.</p> <p>4 Q. The '80s? '90s?</p> <p>5 A. Oh, 2000s.</p> <p>6 Q. 2000s.</p> <p>7 Okay. Do you think it was</p> <p>8 before or after 2010?</p> <p>9 A. Probably before.</p> <p>10 Q. Okay. And did you make any</p> <p>11 changes based on -- to your job and your job</p> <p>12 duties based on that information that you</p> <p>13 received from Karen Harper about Florida?</p> <p>14 A. Well, I believe, as you can see</p> <p>15 from the documents that we were reviewing or</p> <p>16 from what we talked about, that there was a</p> <p>17 growing concern from the DEA about diversion,</p> <p>18 and that's part of the reason why we enhanced</p> <p>19 our -- our program that we had in place,</p> <p>20 suspicious order program.</p> <p>21 Q. Okay. And so you believe that</p> <p>22 the change in your suspicious order program</p> <p>23 was because of this information about</p> <p>24 Florida?</p> <p>25 MR. TSAI: Object to the form.</p>	<p>1 people were traveling from other states to</p> <p>2 Florida for the purpose of obtaining opioids?</p> <p>3 A. I was.</p> <p>4 Q. And how did you become aware of</p> <p>5 that?</p> <p>6 MR. TSAI: Objection. Vague as</p> <p>7 to time.</p> <p>8 Go ahead.</p> <p>9 THE WITNESS: Through what I</p> <p>10 was just talking about, information</p> <p>11 that Karen passed on to us.</p> <p>12 QUESTIONS BY MS. HERZFELD:</p> <p>13 Q. Okay. Did you know that people</p> <p>14 from Tennessee specifically were going to</p> <p>15 Florida to get opioids?</p> <p>16 MR. TSAI: Objection. Vague as</p> <p>17 to time.</p> <p>18 THE WITNESS: No, not</p> <p>19 specifically.</p> <p>20 QUESTIONS BY MS. HERZFELD:</p> <p>21 Q. Since 2000, that people were</p> <p>22 going from Tennessee to Florida to get</p> <p>23 opioids, were you aware of that?</p> <p>24 A. Was there a question there?</p> <p>25 Q. Yes.</p>

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<p>1 Were you aware of that?</p> <p>2 A. No.</p> <p>3 Q. Okay. Did the suspicious order</p> <p>4 monitoring team monitor Tennessee news</p> <p>5 articles?</p> <p>6 A. No.</p> <p>7 Q. Okay. Did the suspicious order</p> <p>8 monitoring team monitor social media within</p> <p>9 Tennessee?</p> <p>10 A. No.</p> <p>11 Q. Okay. Did the suspicious order</p> <p>12 monitoring team review Tennessee disciplinary</p> <p>13 actions of pharmacists and prescribers?</p> <p>14 A. Not that I'm aware of.</p> <p>15 Q. Okay. Did the suspicious order</p> <p>16 monitoring team review third-party data for</p> <p>17 red flags of diversion in Tennessee?</p> <p>18 A. I don't know what the</p> <p>19 compliance group was monitoring.</p> <p>20 Q. Okay. And that would have been</p> <p>21 done through the compliance group?</p> <p>22 A. Correct.</p> <p>23 Q. Did you ever review IMS Health</p> <p>24 data or any other data to determine</p> <p>25 suspicious orders in Tennessee?</p>	<p>1 to time.</p> <p>2 THE WITNESS: Not that I</p> <p>3 remember.</p> <p>4 QUESTIONS BY MS. HERZFELD:</p> <p>5 Q. Okay. I'm going to ask you</p> <p>6 that question from 2000 to 2010.</p> <p>7 Did you receive any reports</p> <p>8 about distributors distributing to Tennessee</p> <p>9 with issues of abuse and diversion?</p> <p>10 A. I personally did not.</p> <p>11 Q. Okay. And what about from 2010</p> <p>12 until the time that you retired?</p> <p>13 A. I personally did not.</p> <p>14 Q. Okay. Did you ever hear of</p> <p>15 either of those things?</p> <p>16 A. No.</p> <p>17 Q. Okay. Do you know if anybody</p> <p>18 in your team would have knowledge if it</p> <p>19 wasn't you?</p> <p>20 A. I can't speak for them.</p> <p>21 Q. Okay. Whose responsibility</p> <p>22 would it to -- to have that information,</p> <p>23 reports about suspected abuse and diversion</p> <p>24 of distributors --</p> <p>25 A. I believe if there was such</p>
<p style="text-align: center;">Page 315</p> <p>1 A. No, I did not.</p> <p>2 Q. Okay. Would that have been</p> <p>3 within your purview or that would have been</p> <p>4 the compliance department?</p> <p>5 A. That would have been</p> <p>6 compliance.</p> <p>7 Q. Okay. Did the suspicious order</p> <p>8 monitoring team discuss red flags that could</p> <p>9 indicate diversion in Tennessee with you or,</p> <p>10 to your knowledge, to your team?</p> <p>11 A. Say that again.</p> <p>12 Q. Did the suspicious order</p> <p>13 monitoring team discuss red flags that could</p> <p>14 have indicated diversion in Tennessee with</p> <p>15 you, or was there a discussion amongst the</p> <p>16 team?</p> <p>17 A. No.</p> <p>18 Q. Okay.</p> <p>19 A. Not that I remember.</p> <p>20 Q. Okay. Did the suspicious order</p> <p>21 monitoring team receive reports about</p> <p>22 possible abuse or diversion of Mallinckrodt</p> <p>23 opioids by distributors that supplied to</p> <p>24 Tennessee?</p> <p>25 MR. TSAI: Objection. Vague as</p>	<p style="text-align: center;">Page 317</p> <p>1 reports, it would be going to our Karen</p> <p>2 Harper in compliance.</p> <p>3 Q. Okay. And would you have been</p> <p>4 copied on those, or is that information you</p> <p>5 should have had?</p> <p>6 A. Would I have been copied? No,</p> <p>7 not that I can remember.</p> <p>8 Was it -- how it would affect</p> <p>9 my job, I don't think so.</p> <p>10 Q. Okay. What would have been</p> <p>11 your role?</p> <p>12 A. My role?</p> <p>13 Q. Yes, sir.</p> <p>14 A. In the suspicious order</p> <p>15 monitoring program?</p> <p>16 Q. If you had information that a</p> <p>17 supplier that supplied to Tennessee was</p> <p>18 having issues with abuse and diversion, you</p> <p>19 would have a role in that, would you not?</p> <p>20 A. Well, only an aspect if they</p> <p>21 were -- they were placing orders with us that</p> <p>22 would hit our suspicious order monitoring</p> <p>23 program, that would have been my role.</p> <p>24 Q. Okay. So I guess that's my</p> <p>25 question.</p>

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1	A. Okay.	1 Q. Okay. What about any detailing
2	Q. So I'm going to back it up	2 of any Tennessee physicians by anyone at
3	because maybe you didn't understand it.	3 Mallinckrodt, do you have any knowledge of
4	A. Okay.	4 that?
5	Q. So to your knowledge, you never	5 A. No, I do not.
6	had any orders that came through that were	6 Q. Okay. Were you ever present
7	dinged as suspicious orders through your	7 when opioid abuse or diversion issues in
8	suspicious order monitoring team from	8 Tennessee were discussed by any other
9	Tennessee or from suppliers that supplied	9 Mallinckrodt employee?
10	pharmacies in Tennessee?	10 A. No.
11	A. No.	11 Q. Have you ever seen any memos or
12	Q. Okay. Who would know that?	12 paperwork or any sort of a record talking
13	A. To my knowledge, we did not	13 about --
14	have any suspicious orders.	14 A. Not that I can remember.
15	Q. Okay. So you would be the	15 Q. -- abuse and diversion in
16	person who would know that?	16 Tennessee?
17	A. For that period of time, from	17 A. No.
18	2009 to 2010.	18 Q. Okay. Do you know if anyone on
19	Q. Okay. Okay. And after that,	19 the suspicious order monitoring team, while
20	it would have been?	20 you were involved with it, ever discussed any
21	A. I don't remember her name	21 problems with abuse or diversion with law
22	anymore. I had the first name. It was in my	22 enforcement or other officials in Tennessee?
23	notes. I don't -- I'm getting a little -- I	23 A. No, I do not remember that.
24	don't remember her name. She was in the --	24 Q. Okay. Do you know which
25	the rebate group.	25 distributors at Mallinckrodt did business
	Page 319	Page 321
1	Q. Okay. So after you left that	1 with that shipped Mallinckrodt opioids to
2	position, she'd be the one who would know	2 Tennessee?
3	that?	3 A. Which distributors we shipped
4	A. Right.	4 to in Tennessee?
5	MR. TSAI: Objection.	5 Q. Yes, sir.
6	Duplicative.	6 A. I don't recall that, who they
7	MS. HERZFELD: Can't be	7 were.
8	duplicative if he doesn't know the	8 Q. Okay. What types of records
9	name.	9 would show who those were, the distributors
10	MR. TSAI: No, this question	10 that shipped to Tennessee?
11	was asked before.	11 A. Order processing records.
12	QUESTIONS BY MS. HERZFELD:	12 Q. Okay. Anything else?
13	Q. Okay. On -- do you know if	13 A. That would probably -- from my
14	Mallinckrodt's customer service department	14 point of view where I came from, order
15	had a relationship with any pharmacies in	15 processing would be one of the places that
16	Tennessee?	16 records would be kept.
17	A. I do not know that.	17 Q. Okay. Can you think of any
18	Q. Okay. Do you know if any	18 other spots, or is that the only one you can
19	Mallinckrodt employees ever detailed any	19 think of?
20	Tennessee pharmacies?	20 A. That's the only one I can think
21	A. Detailed?	21 of.
22	Q. Went and met with them, like a	22 Q. Okay. Did the suspicious order
23	sales call.	23 monitoring team ever break down how many
24	A. I don't -- I don't have	24 particular pills were being shipped to a
25	knowledge of that.	25 state, on a kind of state-by-state basis?

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<p>1 Did you ever look at that in the aggregate?</p> <p>2 A. By state by state?</p> <p>3 Q. Yes, sir.</p> <p>4 A. Not that I'm aware of.</p> <p>5 Q. Okay. Or by ZIP code or by</p> <p>6 city?</p> <p>7 A. No.</p> <p>8 Q. Okay. Do you know what</p> <p>9 percentage of Mallinckrodt opioids were sent</p> <p>10 to Tennessee?</p> <p>11 A. I do not.</p> <p>12 Q. Okay. Do you know if there was</p> <p>13 ever a consideration in the suspicious order</p> <p>14 monitoring team about the number of opioids</p> <p>15 shipped to a particular area compared to that</p> <p>16 area's population?</p> <p>17 A. No.</p> <p>18 Q. Okay. So other than we talked</p> <p>19 about Florida a little bit just a few minutes</p> <p>20 ago, you said that the changes were</p> <p>21 generally -- I'm paraphrasing you, so tell me</p> <p>22 if I'm saying it incorrectly -- that the DEA</p> <p>23 generally had some concerns about diversion</p> <p>24 generally, and you knew specifically about</p> <p>25 this issue in Florida.</p>	<p>1 that would be a possibility.</p> <p>2 Q. Okay. But to your knowledge,</p> <p>3 from your perspective, everything was the</p> <p>4 same?</p> <p>5 A. From my perspective, correct.</p> <p>6 Q. Okay. And so that would go for</p> <p>7 Tennessee as well. Tennessee was never</p> <p>8 treated differently than any other state?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. Did you ever have any</p> <p>11 discussion with any distributors about</p> <p>12 problem prescribers in Tennessee?</p> <p>13 A. No.</p> <p>14 Q. Did you ever hear a discussion</p> <p>15 of problem prescribers in Tennessee?</p> <p>16 A. No.</p> <p>17 Q. Okay. And what about problem</p> <p>18 pharmacies?</p> <p>19 A. No.</p> <p>20 Q. Okay. Do you know if any</p> <p>21 distributor orders going to Tennessee ever</p> <p>22 appeared to be in your peculiar order report</p> <p>23 or suspicious order report?</p> <p>24 A. I don't remember. I don't</p> <p>25 remember.</p>
<p style="text-align: center;">Page 323</p> <p>1 A. Correct.</p> <p>2 Q. Based on that information, did</p> <p>3 you treat Florida any differently than any</p> <p>4 other state in performing your job</p> <p>5 responsibilities?</p> <p>6 A. Not my job responsibilities.</p> <p>7 Our -- our reports from -- would --</p> <p>8 nationally for all that would -- would take a</p> <p>9 look at orders that were being processed from</p> <p>10 Florida, like any other order, and kick out</p> <p>11 peculiar orders from them.</p> <p>12 Q. Okay. So I want --</p> <p>13 A. At that time, yeah.</p> <p>14 Q. I want to make sure I</p> <p>15 understand your answer correctly.</p> <p>16 So Florida would have been</p> <p>17 looked at the same as any other state at that</p> <p>18 point?</p> <p>19 A. From what I remember.</p> <p>20 Q. Okay.</p> <p>21 A. There may have been -- you</p> <p>22 know, we had a compliance group led by Karen</p> <p>23 Harper that would visit distributors and</p> <p>24 that. That may have been one of the areas</p> <p>25 that they keyed in on. I'm not sure, but</p>	<p style="text-align: center;">Page 325</p> <p>1 Q. Is it possible to determine in</p> <p>2 the aggregate, year by year, how many of</p> <p>3 those suspicious orders or peculiar order</p> <p>4 reports were generated for Tennessee? From</p> <p>5 Tennessee?</p> <p>6 A. Is it possible to do that? I</p> <p>7 guess it's possible. I don't know how it</p> <p>8 would be done, but I can't answer it any</p> <p>9 further than that.</p> <p>10 Q. When you put the information</p> <p>11 into the computer or database or whatever --</p> <p>12 A. Right. And looking at how far</p> <p>13 back you're talking about, whether the data</p> <p>14 is still available, someone from -- from IS</p> <p>15 or whatever would have to put together a</p> <p>16 report, if they could, of the history of</p> <p>17 orders that were placed by companies in</p> <p>18 Tennessee.</p> <p>19 Q. Okay. And do you know what the</p> <p>20 name of that database was or if there was --</p> <p>21 A. JD Edwards.</p> <p>22 Q. JD Edwards?</p> <p>23 A. That was the order processing</p> <p>24 system.</p> <p>25 Q. Okay. And that's what was used</p>

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1 at the time? 2 A. Yes. 3 Q. Okay. And do you have a 4 designation for state or region or something 5 geographically? 6 A. Yes. 7 Q. Okay. Great. 8 Do you know if there were any 9 Tennessee pharmacies on Mallinckrodt's 10 chargeback restriction list? 11 A. I'm not familiar with the 12 chargeback system. 13 Q. Okay. Do you know if anyone 14 from your team ever communicated with any 15 Tennessee pharmacies? 16 A. No. 17 Q. Did you ever communicate with 18 any Tennessee pharmacies? 19 A. Not that I -- no. 20 Q. Okay. And I'm not -- I may 21 have asked you this question, so if I did, I 22 apologize. 23 You don't recall any suspicious 24 orders coming from Tennessee for diversion or 25 overordering or anything?	1 A. I don't remember. 2 Q. Okay. Did you ever attend any 3 meetings about the DEA investigation of 4 Sunrise Wholesale? 5 A. No, I didn't. 6 Q. Okay. Did you hear about a 7 sting operation in 2009 of -- in Tennessee 8 relating to Sunrise Wholesale in Florida? 9 A. No, I didn't. 10 Q. Okay. Have you ever spoken or 11 do you know a person named Pete Kleissle? 12 A. Doesn't ring a bell. 13 Q. Okay. DEA agent? 14 A. No, doesn't -- sorry. 15 Q. That's okay. 16 Have you ever spoken to a DEA 17 agent, to your knowledge? 18 A. Not that I can remember. 19 Q. Okay. 20 A. It was -- most of our 21 communication with the DEA was through Karen 22 Harper's group. 23 Q. Okay. 24 A. Our compliance group, I should 25 say.
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1 A. No. 2 Q. Okay. Do you have any 3 familiarity with Sunrise Wholesale? 4 A. I've heard of them. 5 Q. In Delray Beach, Florida? 6 A. Yes. 7 Q. Okay. Did you have any 8 involvement with Sunrise Wholesale while you 9 were at Mallinckrodt? 10 A. As far as what? 11 Q. Any discussions about them? 12 Meetings? 13 A. I remember Sunrise being 14 discussed. What was discussed, I don't 15 remember. 16 Q. Okay. Do you recall Tennessee 17 being mentioned in relation to Sunrise? 18 A. No. 19 Q. Okay. Do you know if Sunrise 20 Wholesale had been flagged for suspicious 21 orders or peculiar orders? 22 A. I don't remember. 23 Q. Okay. Did you ever learn at 24 some point that Sunrise Wholesale was being 25 investigated by the DEA?	1 Q. Okay. Have you ever heard of 2 Dr. Barry Schultz? 3 A. Does not ring a bell. 4 Q. Okay. And do you know who 5 would have been involved in a decision to 6 continue to ship to Sunrise Wholesale after 7 July of 2009? 8 A. Who would have been involved? 9 Q. Who would have made that 10 decision. 11 Would that have been you? 12 A. Whether we were going to -- no, 13 that was above my pay grade. 14 Q. Okay. 15 A. It would have been our DEA 16 compliance group. They would have informed 17 us that we were no longer going to ship to 18 them. 19 Q. Okay. And if they didn't, you 20 would just continue shipping to them if 21 they're an existing customer? 22 MR. TSAI: Object to the form. 23 THE WITNESS: That's -- that's 24 asking me to -- I don't -- I'll answer 25 that by saying I don't think we do,

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<p>1 because the compliance group would 2 have informed us not to ship to them 3 anymore.</p> <p>4 QUESTIONS BY MS. HERZFELD:</p> <p>5 Q. If there was already a raid?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. But you don't have any 8 knowledge specifically about --</p> <p>9 A. No, I don't.</p> <p>10 Q. -- Sunrise?</p> <p>11 Okay. Do you know who Steve 12 Becker is?</p> <p>13 A. I do.</p> <p>14 Q. Who is Steve Becker?</p> <p>15 A. Steve Becker was a salesman.</p> <p>16 Q. Okay. A salesman at 17 Mallinckrodt?</p> <p>18 A. Correct.</p> <p>19 Q. Okay. Do you recall attending 20 a meeting with Steve Becker in July of 2010 21 to talk about the oxy situation?</p> <p>22 A. I don't recall it.</p> <p>23 Q. Have you ever been in a meeting 24 with Steve Becker that you've talked about 25 diversion or oxy or anything like that?</p>	<p>1 Q. Did you ever go to Cincinnati 2 for a meeting to discuss suspicious order 3 monitoring?</p> <p>4 A. I believe we did.</p> <p>5 Q. Okay. When do you think that 6 was?</p> <p>7 A. I don't remember. Probably 8 2009.</p> <p>9 Q. Okay. And do you recall what 10 the purpose of the meeting was?</p> <p>11 A. To discuss their suspicious 12 order program, look to observe their 13 facility.</p> <p>14 Q. When you say "them," who do you 15 mean?</p> <p>16 A. Oh, I'm sorry.</p> <p>17 Q. That's okay.</p> <p>18 A. I believe -- I believe Karen -- 19 well, I think Karen Harper was involved, but 20 I don't remember for sure. I believe our 21 VP -- VP of sales was involved. She went 22 along. And also our director of marketing 23 was also involved.</p> <p>24 But our purpose, I believe, at 25 the time was to see what monitoring they had</p>
<p>1 A. I don't remember.</p> <p>2 Q. Okay. Do you recall ever 3 discussing Tennessee with Steve Becker?</p> <p>4 A. No.</p> <p>5 Q. Okay. Do you know a 6 distributor named KeySource Medical, Inc.?</p> <p>7 A. I remember the name.</p> <p>8 Q. Okay. Do you remember anything 9 specific about them?</p> <p>10 A. They were a customer at some 11 point.</p> <p>12 Q. Okay. In Florida maybe?</p> <p>13 A. I would be guessing that they 14 were in Florida.</p> <p>15 Q. Okay. Do you know if you had 16 any interaction with KeySource Medical?</p> <p>17 A. No.</p> <p>18 Q. Okay. Do you know if that -- 19 you ever heard anybody mention or read in any 20 documents any interactions between KeySource 21 Medical and Tennessee?</p> <p>22 A. No.</p> <p>23 Q. Okay. Have you ever been to 24 Cincinnati?</p> <p>25 A. I have been to Cincinnati.</p>	<p>1 in their system for suspicious orders, that 2 type of thing.</p> <p>3 Q. And when you say "monitoring in 4 their system" --</p> <p>5 A. What their suspicious order 6 program was, if they had one, and what 7 their -- because we were doing some due 8 diligence, as I mentioned earlier, that we 9 were trying to outreach to other companies 10 that we dealt with to see if we could help 11 them in developing suspicious order reporting 12 if they didn't have it already.</p> <p>13 Q. And which company were you 14 visiting?</p> <p>15 A. I don't remember the name.</p> <p>16 Q. Okay. You just knew it was in 17 Cincinnati and there was a big group of 18 people?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Okay. And you didn't 21 attend a DEA meeting in 2011 in Arlington, 22 Virginia?</p> <p>23 A. No.</p> <p>24 Q. Okay. I'm assuming that 25 because you said you've never met a DEA</p>

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<p>1 agent.</p> <p>2 A. Right.</p> <p>3 Q. Okay. Do you know anything</p> <p>4 about Masters Pharmaceutical?</p> <p>5 A. I remember the name, yes.</p> <p>6 Q. Okay. And did you interact at</p> <p>7 all with Masters Pharmaceutical?</p> <p>8 A. Were they in Cincinnati?</p> <p>9 Q. I wish I could answer that</p> <p>10 question for you. I can't.</p> <p>11 A. I don't -- okay. Because I</p> <p>12 couldn't remember what the name of the</p> <p>13 company was in Cincinnati.</p> <p>14 Q. I don't have that information.</p> <p>15 A. Did I interact personally with</p> <p>16 them?</p> <p>17 Q. Yes.</p> <p>18 A. No.</p> <p>19 Q. Do you know if anyone from your</p> <p>20 team did?</p> <p>21 A. By "your team," do you mean</p> <p>22 compliance people?</p> <p>23 Q. Yes, sir.</p> <p>24 A. I'm sure there was some</p> <p>25 inter -- I believe so.</p>	<p>1 A. I remember discussions about</p> <p>2 Harbor being reviewed -- reviewed by the DEA.</p> <p>3 Q. Okay. Do you remember who was</p> <p>4 having those discussions?</p> <p>5 A. The DEA.</p> <p>6 Q. Okay. And do you recall who</p> <p>7 told you?</p> <p>8 A. I believe that was probably</p> <p>9 from Karen Harper.</p> <p>10 Q. Okay. And did Ms. Harper or</p> <p>11 anyone else ever mention Tennessee in</p> <p>12 connection with the Harbor Medical Group?</p> <p>13 A. Not that I remember.</p> <p>14 MS. HERZFELD: Okay. I don't</p> <p>15 think I have any further questions for</p> <p>16 this witness at this time. Thank you.</p> <p>17 VIDEOGRAPHER: We're going off</p> <p>18 the record at 5:46 p.m.</p> <p>19 (Off the record at 5:46 p.m.)</p> <p>20 VIDEOGRAPHER: We are back on</p> <p>21 the record at 5:47 p.m.</p> <p>22 CROSS-EXAMINATION</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. Mr. Rausch, do you recall your</p> <p>25 testimony earlier today regarding Mr. Howard</p>
<p style="text-align: center;">Page 335</p> <p>1 Q. Okay. Do you recall them</p> <p>2 having any particular issues with suspicious</p> <p>3 or peculiar orders?</p> <p>4 A. I don't remember.</p> <p>5 Q. Okay. Do you remember anybody</p> <p>6 particularly kind of being repeat customers</p> <p>7 for issues for suspicious or peculiar orders?</p> <p>8 A. We didn't have -- in the time</p> <p>9 frame that I had, we didn't have any</p> <p>10 suspicious orders.</p> <p>11 Q. Okay. So you've -- as was</p> <p>12 already discussed, you would track those down</p> <p>13 and eventually the order would go through?</p> <p>14 A. Right.</p> <p>15 Q. Okay. What about the Harbor</p> <p>16 Medical Group in Livonia, Michigan, do you</p> <p>17 recall any interactions with them?</p> <p>18 A. I remember the name.</p> <p>19 Q. Okay. And do you remember</p> <p>20 anything particularly about them?</p> <p>21 A. As far as --</p> <p>22 Q. Suspicious orders?</p> <p>23 A. -- compliance, that type of</p> <p>24 thing?</p> <p>25 Q. Yes, sir.</p>	<p style="text-align: center;">Page 337</p> <p>1 Davis?</p> <p>2 A. I do.</p> <p>3 Q. Have you ever met Howard Davis?</p> <p>4 A. Not that I can recall.</p> <p>5 Q. Have you ever spoken with</p> <p>6 Howard Davis?</p> <p>7 A. Not that I can recall.</p> <p>8 Q. Do you know whether Howard</p> <p>9 Davis had any experience as of November 2010</p> <p>10 in regard to developing or implementing any</p> <p>11 suspicious order monitoring program?</p> <p>12 A. I do not know if he did or not.</p> <p>13 Q. Could you pull up Exhibit 10?</p> <p>14 A. (Witness complies.)</p> <p>15 Q. And if I could refer you to</p> <p>16 Section 5, entitled "Background</p> <p>17 Documentation."</p> <p>18 A. Okay.</p> <p>19 Q. Is it your understanding that</p> <p>20 this is Mr. Davis' personal recommendation as</p> <p>21 to additional background documentation for</p> <p>22 Mallinckrodt to request for its customers?</p> <p>23 A. That's my understanding.</p> <p>24 Q. Are Mallinckrodt's customers</p> <p>25 individual pharmacies?</p>

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<p>1 A. No.</p> <p>2 Q. Are Mallinckrodt's customers</p> <p>3 patients or end users?</p> <p>4 A. No.</p> <p>5 Q. Are Mallinckrodt's customers</p> <p>6 physicians or other prescribers?</p> <p>7 A. No.</p> <p>8 Q. Are Mallinckrodt's customers</p> <p>9 distributors or other manufacturers?</p> <p>10 A. Yes.</p> <p>11 Q. If you could go back to</p> <p>12 Section 5, and do you see the bullet point --</p> <p>13 one of the background documentation items</p> <p>14 recommended by Mr. Davis as of November 2010</p> <p>15 in this memo is "Do they self-medicate?"</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Could Mallinckrodt ask a</p> <p>19 distributor whether it self-medicates?</p> <p>20 MR. KAWAMOTO: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: No.</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. If you could go to the very</p> <p>25 next bullet point: "Are they treating family</p>	Page 339	<p>1 MR. TSAI: No further</p> <p>2 questions.</p> <p>3 MR. KAWAMOTO: Okay. I believe</p> <p>4 I'm permitted to recross.</p> <p>5 MR. TSAI: Yes. It's a</p> <p>6 minute-for-minute for recross.</p> <p>7 MR. KAWAMOTO: I guess I have</p> <p>8 seven minutes or six minutes.</p> <p>9 REDIRECT EXAMINATION</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. So, Mr. Rausch, your</p> <p>12 counsel asked you a number of questions</p> <p>13 regarding Section 5 relating to the types of</p> <p>14 information that could be solicited; is that</p> <p>15 fair?</p> <p>16 A. That's correct.</p> <p>17 Q. Could this information have</p> <p>18 been solicited from a distributor's</p> <p>19 customers?</p> <p>20 A. From a distributor's customer?</p> <p>21 Q. Yes.</p> <p>22 A. I guess it could be.</p> <p>23 Q. So this is information that</p> <p>24 could be gathered on Mallinckrodt -- on the</p> <p>25 customers of Mallinckrodt's customer,</p>
<p>1 members?"</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Could Mallinckrodt ask one of</p> <p>5 its distributor customers whether it is</p> <p>6 treating family members?</p> <p>7 A. No.</p> <p>8 Q. Could Mallinckrodt, looking at</p> <p>9 the next bullet point, ask one of its</p> <p>10 distributor customers how many patients do</p> <p>11 they see daily?</p> <p>12 A. No.</p> <p>13 Q. Going to the next bullet point,</p> <p>14 recommended by Mr. Davis, could Mallinckrodt</p> <p>15 ask one of its distributor customers about</p> <p>16 the number of patients to whom they dispense</p> <p>17 controlled substances?</p> <p>18 A. No.</p> <p>19 Q. Do these recommendations even</p> <p>20 make sense for a manufacturer like</p> <p>21 Mallinckrodt?</p> <p>22 A. Not to me.</p> <p>23 Q. And do you agree with</p> <p>24 Mr. Davis' recommendations here?</p> <p>25 A. No.</p>	Page 341	<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And using the chargeback data,</p> <p>4 Mallinckrodt could -- Mallinckrodt had an</p> <p>5 understanding of who the distributor's</p> <p>6 customers were; is that correct?</p> <p>7 MR. TSAI: Object to the form.</p> <p>8 THE WITNESS: I don't know how</p> <p>9 the chargeback data worked. I was not</p> <p>10 familiar with that process.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. Is it your understanding that</p> <p>13 the chargeback data could be used to identify</p> <p>14 the end users?</p> <p>15 A. I believe so.</p> <p>16 Q. Okay.</p> <p>17 A. But to -- do they</p> <p>18 self-medicate? I don't think they could find</p> <p>19 that information out and some of the other</p> <p>20 questions here.</p> <p>21 MR. KAWAMOTO: Okay. No</p> <p>22 further questions.</p> <p>23 THE WITNESS: Okay.</p> <p>24 VIDEOGRAPHER: We're going off</p> <p>25 the record at 5:51 p.m.</p>

1 (Deposition concluded at 5:51 p.m.) 2 ----- 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	Page 342 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	Page 343 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	Page 344 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
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